

**VETERANS HEALTH ADMINISTRATION  
OFFICE OF PATIENT CARE SERVICES  
TECHNOLOGY ASSESSMENT PROGRAM**

**BRIEF OVERVIEW  
Regionalization of Surgical Services**

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# TECHNOLOGY ASSESSMENT PROGRAM

*An Effective Resource for Evidence-based Managers*

VA's Technology Assessment Program (TAP) is a national program within the Office of Patient Care Services dedicated to advancing evidence-based decision making in VA. TAP responds to the information needs of senior VA policy makers by carrying out systematic reviews of the medical literature on health care technologies to determine "what works" in health care. "Technologies" may be devices, drugs, procedures, and organizational and supportive systems used in health care. TAP reports can be used to support better resource management.

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## A SUMMARY FOR HTA REPORTS

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This summary form is intended as an aid for those who want to record the extent to which an HTA report meets the 17 questions presented in the checklist. It is NOT intended as a scorecard to rate the standard of HTA reports – reports may be valid and useful without meeting all of the criteria that have been listed.

### Brief Overview: Regionalization of Surgical Services

April, 2009

Item	Yes	Partly	No
<b>Preliminary</b>			
1. Appropriate contact details for further information?	√		
2. Authors identified?	√		
3. Statement regarding conflict of interest?			√
4. Statement on whether report externally reviewed?		√	
5. Short summary in non-technical language?			√
<b>Why?</b>			
6. Reference to the question that is addressed and context of the assessment?	√		
7. Scope of the assessment specified?	√		
8. Description of the health technology?		√	
<b>How?</b>			
9. Details on sources of information?	√		
10. Information on selection of material for assessment?	√		
11. Information on basis for interpretation of selected data?	√		
<b>What?</b>			
12. Results of assessment clearly presented?	√		
13. Interpretation of assessment results included?	√		
<b>What Then?</b>			
14. Findings of the assessment discussed?	√		
15. Medico-legal implications considered?			√
16. Conclusions from assessment clearly stated?	√		
17. Suggestions for further actions?	√		

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**ABBREVIATIONS IN THIS REVIEW**

<b>AAA</b> , abdominal aortic aneurysm	<b>IT</b> , information technology
<b>AAMC</b> , American Association of Medical Colleges	<b>JCAHO</b> , Joint Commission on Accreditation of Healthcare Organizations
<b>ACC</b> , American College of Cardiology	<b>LOS</b> , length of stay
<b>AHA</b> , American Heart Association	<b>LVH</b> , low volume hospital
<b>AHRQ</b> , Agency for Healthcare Research and Quality (US)	<b>MI</b> , myocardial infarction
<b>AMI</b> , acute myocardial infarction	<b>MVH</b> , medium volume hospital
<b>CABG</b> , coronary artery bypass graft	<b>NCI</b> , National Cancer Institute (US)
<b>CCI</b> , Charlson comorbidity index	<b>NHS</b> , National Health Service (UK)
<b>CEA</b> , carotid endarterectomy	<b>NI</b> , nosocomial infection
<b>CDC</b> , Centers for Disease Control and Prevention (US)	<b>NIH</b> , National Institutes of Health (US)
<b>CHF</b> , congestive heart failure	<b>NIS</b> , Nationwide Inpatient Sample
<b>CICSP</b> , Continuous Improvement in Cardiac Surgery Program	<b>NSQIP</b> , National Surgical Quality Improvement Program
<b>CMS</b> , Centers for Medicare and Medicaid Services (Formerly HFCA)	<b>NS</b> , not significant
<b>CON</b> , certificate of need	<b>OAR</b> , open aortic repair
<b>COPD</b> , chronic obstructive pulmonary disease	<b>O/E</b> , Observed-to-expected ratio
<b>CPT</b> , current procedural terminology	<b>OPCS</b> , Office of Patient Care Services
<b>CQI</b> , continuous quality improvement	<b>OR</b> , operating room
<b>CRC</b> , colorectal cancer	<b>PCI</b> , percutaneous coronary intervention
<b>DVT</b> , deep vein thrombosis	<b>PD</b> , pancreaticoduodenectomy
<b>EB</b> , evidence-based	<b>PR</b> , pancreatic resection
<b>EPOC</b> , Effective Practice and Organization of Care (Cochrane review group/trial register)	<b>QA</b> , quality assurance
<b>EVAR</b> , endovascular aneurysm repair	<b>QI</b> , quality improvement
<b>FY</b> , fiscal year	<b>RAAA</b> , ruptured abdominal aortic aneurysm
<b>GEE</b> , generalized estimating equation	<b>RCT</b> , randomized controlled trial
<b>HCUP</b> , Healthcare Cost and Utilization Project (US AHRQ)	<b>RHR</b> , revision hip replacement
<b>HES</b> , Hospital Episode Statistics (UK)	<b>SEER</b> , Surveillance, Epidemiology, and End Results registry (CMS, US)
<b>HPB</b> , hepato-pancreato-biliary (surgery)	<b>STS</b> , soft tissue sarcoma
<b>HR</b> , hazard ratio	<b>STS</b> , Society of Thoracic Surgeons
<b>HRR</b> , hospital referral region	<b>TAAG</b> , Technology Assessment Advisory Group
<b>HSR&amp;D</b> , Health Services Research and Development	<b>THA</b> , total hip arthroplasty
<b>HVH</b> , high volume hospital	<b>THR</b> , total hip replacement
<b>ICU</b> , intensive care unit	<b>TME</b> , total mesorectal excision (for rectal cancer)
<b>IDC</b> , infiltrating ductal carcinoma (of the female breast)	<b>TQM</b> , total quality management
<b>IHI</b> , Institute for Healthcare Improvement	<b>UHC</b> , University Healthsystem Consortium (US)
<b>IMA</b> , internal mammary artery	<b>UK</b> , United Kingdom
<b>INAHTA</b> , International Network of Agencies for health Technology Assessment	<b>UN</b> , United Nations
<b>IOM</b> , Institute of Medicine	<b>VAMC</b> , Veterans Administration medical center
	<b>VHVH</b> , very high volume hospital
	<b>VLVH</b> , very low volume hospital

## BRIEF OVERVIEW: Regionalization of Surgery

### OBJECTIVE

*“VHA is in the unique position of having to distribute comprehensive healthcare across the entire country. Often we are challenged to do this for geographical reasons as well as logistical considerations. Recently, we have been concerned about the quality of procedural practice in smaller VAMCs. While the relationship between case volume and outcomes is well documented for both facility and provider, we have to resist the temptation to be dismissive of lower volume centers. The obvious solution is to leverage the “hub and spoke” network, but often this imposes great hardship on patients, and such is contrary to our commitment to “patient centered care”. Given this conundrum, we need to consider how we can best provide surgical services in smaller facilities without imposing undue jeopardy on patients. What is the state-of-the-art for rural surgery in the US and elsewhere in the world (training programs for rural surgeons, their scope of practice, how rural facilities are structured to support high quality in their ORs, governance and oversight specific to rural surgery)?” Jesse (2008).*

### INTRODUCTION

*“Despite this growing interest in assessing surgical quality there remains controversy about how best to identify high-quality hospitals for individual procedures. Hospital procedure volume is currently among the most widely used quality indicators. There remains little doubt that volume is inversely related to operative mortality with many procedures. Nonetheless, critics decry volume as a crude surrogate for quality and a poor predictor of individual hospital performance. Instead, many think that surgical quality is best judged by direct outcome measures, including operative mortality. For many procedures, however, hospital mortality rates may be hampered by sample size problems and thus may be too imprecise to meaningfully reflect quality of care.” Birkmeyer (2006).*

*“Because higher hospital procedure volume is associated with better outcomes for many high-risk procedures, regionalization to higher-volume hospitals has been proposed as a way to improve quality of surgical care. The potential impact of such policies on small rural hospital volume and revenue is unknown...there remains considerable apprehension on the part of rural surgeons and hospital administrators, where high procedure volumes are difficult (if not impossible) to sustain. Rural surgeons worry that they will lose operative skills if unable to perform procedures of greater complexity (e.g., facing a ruptured abdominal aortic aneurysm after years of referring elective aneurysms to larger hospitals) or express simple concerns about the ennui of a leaner surgical palette. Because volume does not perfectly correlate with outcomes (i.e., some low-volume practices have excellent outcomes), some rural surgeons might also believe that volume-based regionalization policies are unfairly discriminatory. Rural hospital administrators, who are already struggling to recruit and retain surgeons, are naturally uneasy about policies that might make surgeons less likely to practice in rural settings ”. Chappel (2006).*

*“Numerous reports have documented a volume-outcome relationship for complex medical and surgical care, although many such studies are compromised by the use of discharge abstract data, inadequate risk adjustment, and problematic statistical methodology. Because of the volume-outcome association, and because valid outcome measurements are unavailable for many procedures, volume-based referral strategies have been advocated as an alternative approach to health-care quality improvement. This is most appropriate for procedures with the greatest outcome variability between low-volume and high-volume providers, such as esophagectomy and pancreatectomy, and for particularly high-risk subgroups of patients. Whenever possible, risk-adjusted outcome data should supplement or supplant volume standards, and continuous quality improvement programs should seek to emulate the processes of high-volume, high-quality providers...” Shahian (2003).*

Tancredi (1988) provides a comprehensive overview of the state of quality definitions and measurement at that time, worth reiteration here for its coverage of core quality literature:

*“One of the most complex and perhaps least understood concepts in the contemporary rhetoric surrounding health care issues is quality of care. The notion of quality has generated an enormous volume of literature over the past fifteen to twenty years, and has been the subject of serious academic attention. Scholars like Donabedian and Brook have contributed greatly to our understanding of how quality of care can be assessed in the health care system (in 1980, -82; and -73, respectively). Despite their important contributions, the concept of quality remains elusive. “Quality of care” conjures up a wide range of meanings, from the “perfectibility” of techniques of clinical interventions in minimizing symptoms and morbidity, to decreases in mortality rates. To understand quality of care in a particular context, we must ask several questions: What quality of care is being specified, by whom, for whom, and for what reason?...”*

*The notion of quality of care is complicated further by its frequent conflation with economic considerations. Although there is a relationship between the cost of care and its quality, there is no clear cut agreement on the threshold level of quality or the acceptable cost of attaining it. Furthermore, the parameters used in accessing acceptable quality of care differ, based upon preferences and ideologies. The ideological aspect of quality of care rests on its slippery and highly relativistic definition, which lends to its use by providers in order to achieve their own objectives...”*

Muir Gray (1997) updates the discussion without fundamentally changing it:

*“When outcome measures were first proposed they were hailed as the ultimate measures that would enable the patient and purchaser to distinguish a good service from a bad service. Further experience with outcome-based measures of quality dimmed enthusiasm for two main reasons:*

- 1. The health status of an individual, a group of patients or a population is determined by several factors other than the quality of the service, notably, severity of illness and state of health before treatment.*
- 2. The collection of valid information about outcomes in ordinary service settings is difficult because of the problems of obtaining accurate information on the presence of other complicating diseases.”*

Sackett (1991) brings the preceding discussion points together in a list of evaluation criteria for articles about quality of care:

- “Did the study focus on what clinicians actually do?*
- Have the clinical acts under study been shown to do more good than harm?*
- Were the clinical acts or processes measured in a clinically sensible and valid way?*
- Were both clinical and statistical significance considered?”*

Birkmeyer (2002), Bentrem (2005), and Luft (2007) reiterate one of the core discussions in surgical quality: the volume-outcome relationship first explored by research conducted in the 1980s and explicit to this overview:

*“Despite the recent interest in surgical volume, many question the applicability of previous research on volume and outcome to current practice. First, many studies of volume and outcome are outdated. Given that the surgical mortality associated with many procedures has fallen considerably since these studies were conducted, the relative importance of the volume of procedures performed may be declining. Second, most published studies on volume and outcome have used state-level data bases or regional populations that are served by a small number of high-volume centers. Whether their results are broadly generalizable is uncertain. And finally, although some procedures (e.g., cardiac surgery) have been studied extensively, the relative importance of volume to mortality with many other high-risk procedures either has not been explored or has been studied in samples that were too small to permit assessment of performance at all meaningful levels of hospital volume.” (Birkmeyer 2002).*

*“Most studies focus on short-term operative mortality and morbidity, but increasingly data suggest additional long-term survival benefit is also volume dependent...Surgical volume is used as a presumed or indirect measure of surgical expertise and/or specialization. Volume remains a crude measure, and when grouped into high versus low or high versus intermediate versus low, statistical significance can be*

shown, but results are not linear and depend on the particular operation chosen for comparison.” (Bentrem, 2005).

*“There is wide acceptance of the hypothesis that, other things being equal, the quality of care improves with the experience of those providing it. If true, surgical mortality rates should be lower in hospitals performing higher volumes of a given procedure. Also, the “experience effect” should be more pronounced in more complex procedures. The “experience curve” or “learning curve,” describing a logarithmic decline in unit costs as a function of cumulative production experience, has been widely recognized and well documented in industrial economics. The experience hypothesis – if true – would have important implications for the organization of medical care: optimal quality as well as cost savings from economies of scale and experience could potentially be realized through “regionalization”. Our search of the medical literature has yielded little statistical documentation for the hypothesis, and no broadly based empirical evidence of what volumes are required to obtain these benefits for specific procedures.” (Luft, 2007).*

Luft (still 2007) concludes:

*“These results may be explained by the effect of volume or experience on mortality, or by the referral of a larger volume of patients to those institutions or surgeons known to have better outcomes. These results may also reflect, in part, differences in patient mix not measured by our statistical controls; for example, institutions with better outcomes may be able to justify operating on patients with less severe disease. The case for regionalization does not depend on the relative importance of these determinants, however. Accordingly, we should not postpone developing policies to encourage the regionalization of those procedures whose outcomes are markedly less satisfactory in low-volume hospitals.”*

Christian (2005) provides a dissenting perspective:

*“There are also opponents to policy initiatives based on the volume-outcome relationship. These focus primarily on the implications of such policy changes, including long travel times for patients in rural areas, the creation of a two-tiered medical system for those rural patients unwilling or unable to travel, unintended changes in referral patterns, a lack of continuity in postoperative care, and the possibility of further overwhelming already busy high-volume centers...The etiology of the relationship between volume and outcome is not well understood...Additionally, it is widely recognized that volume is not a direct measure of quality. Rather, it is a proxy for other measures, such as structure and process characteristics, which more accurately reflect quality of care...”*

*In surgery, many suggested quality measures relate to structure. The teaching status of hospitals, the existence of specialized intensive care units and operating rooms, and staffing ratios are all examples of structural characteristics that could contribute to the observed volume-outcome relationship, but studies to support this are limited...”*

*Mortality is the most attractive outcome measure due to its ease of measurement, particularly in administrative databases. Yet mortality is subject to the limitation that it is a rare event for most surgical procedures in modern surgical practice...”*

*Given the lack of consensus on using outcome as opposed to process measures and the limitations of mortality as a quality measure, it seems dangerous to take this one step further to use volume as a proxy to estimate quality based solely on its relationship with the outcome of mortality.” Christian (2005).*

Berwick (2003) provides a fitting closing to a discussion of quality for the purposes of this review:

*“In the pursuit of health care quality improvement, measurement is necessary but is no more sufficient than measuring a golf score makes for better golf...measurement must be in context of a larger system of improvement... It begins with the purpose of the system of care and the set of national goals selected in support of that purpose. One way to define a goal more clearly is to specify its metric. No such metric is a perfect representation of a goal, but many metrics may be useful. For example, the metric “Adverse Drug Events” is a highly incomplete but rather useful metric to study the goal to “to improve safety...”*

*Health services research has had some remarkable successes in developing useful quantitative tools to measure many dimensions of quality. Practical, reliable, and valid measurements exist today for such complex quality dimensions as patient satisfaction, severity-adjusted surgical mortality rates,*



*appropriateness of tests and therapies, and functional status outcomes in chronic disease. Less mature, but very promising, measurements are now in development for even more performance characteristics such as patient safety, pain control, and the quality of preventive practice...*

*Clear purpose, focused goals, and valid and reliable performance metrics set the stage for the use of measurement to pursue changes that are improvements... two different – although linked and potentially synergistic pathways: Pathway I relies primarily on the act of selection (of the population or segment or the organization under evaluation and its distribution characteristics) to improve quality; Pathway II relies on process change. In a complete improvement strategy, both pathways are important."*

Although VHA has invested in a risk-adjusted surgical outcome quality monitoring model (DePalma, 2006; VHA, 2007), the debate over relative superiority of process versus outcome measures for surgical quality control continues:

*"...errors that are not frequent or do not result in death cannot be identified. Consequently the detection of adverse events may not trigger changes to the process of care. Assessment of outcome as the sole method of measuring and improving quality is thus flawed in theory and in practice...Quality of care should be viewed in terms of both process and outcome. A single outcome is the result of many individual processes or steps, both beneficial and deleterious, in addition to the underlying disease. Although not all errors result in adverse outcomes, their identification offers direct potential for improvement."* Stevenson (2007).

*"Using data adjusted for patient preoperative risk, the NSQIP compares the performance of all VA hospitals using the ratio of observed to expected adverse events. These results are provided to each hospital and used to identify areas for improvement. Since the NSQIP's inception in 1994, the VA has reported consistent improvements in all surgery performance measures..."* Fink (2002).

Berwick (1991) contrasts "old way" and "new way" approaches to quality and its improvement:

*"The tools of modern quality planning, control, and improvement—rooted in decades of development in statistics, engineering, operations research, and other sciences—are powerful. Taught to the workforce as a whole in easily mastered forms, these same tools can lead to "company-wide" quality management, involving everyone in improvement of daily work..."*

*But the lessons from other industries teach us that these technical tools cannot thrive on an organization-wide basis in all management cultures. Certain management methods help the quality effort flourish, while other methods cause the same technical tools to wither. The logic of this interaction between **organizational culture** and **organizational skill** is not hard to see..."*

Finally, it is plausible to hypothesize that higher volume surgical services may be less selective for good risk patients and that such services might actually have worse risk-adjusted outcomes.

**Figure 1: “Old way” and “new way” approaches to quality improvement**  
Adapted from Berwick (1991)

Issue	Old way	New Way
Global approach	Quality is fine	Quality must be better
What makes excellence or flaws?	<ul style="list-style-type: none"> <li>• People are the problem and motivation is the answer.</li> <li>• Blame is useful and reward secures excellence.</li> </ul>	<ul style="list-style-type: none"> <li>• Quality and its flaws lie in processes.</li> <li>• Most trouble is built into processes in which people find themselves trapped.</li> </ul>
Quality control	<ul style="list-style-type: none"> <li>• Inspection keeps people honest and hard at work.</li> <li>• Measurement drives the unwilling.</li> <li>• Exhortation encourages everyone.</li> <li>• Customers are best protected by careful inspection</li> </ul>	<ul style="list-style-type: none"> <li>• Knowledge of processes through collection and analysis of information is the key to improvement.</li> <li>• Exhortation may insult people.</li> <li>• Inspection is a wasteful way to protect customers.</li> </ul>
The answers	Intuition: <ul style="list-style-type: none"> <li>• Leaders know the answers.</li> <li>• Leaders need to control and convince others.</li> <li>• The source of most problems is easily known.</li> </ul>	Data: <ul style="list-style-type: none"> <li>• Collection and analysis of information will help control wasteful managerial effort.</li> <li>• The source of most problems is known only through systematic study of processes.</li> </ul>
Improvement	<ul style="list-style-type: none"> <li>• If individuals do their own jobs properly, the whole will be optimal.</li> </ul>	<ul style="list-style-type: none"> <li>• Most flaws and opportunities to improve occur at boundaries.</li> <li>• Sub-optimization is a costly organizational problem.</li> <li>• People must understand others' jobs as well as their own.</li> </ul>
Customers as problems Vs partners	<ul style="list-style-type: none"> <li>• Control the expectations of customers.</li> <li>• Keep suppliers on their toes through bidding and competition.</li> </ul>	<ul style="list-style-type: none"> <li>• Quality improves better in long-term relationships.</li> <li>• We must continually try to understand the needs of customers and help suppliers to understand our needs</li> </ul>
Resources:	You get what you pay for	The costs of poor quality are enormous
	Don't have the time to do it	Don't have the time not to do it.

Kraus (2005) summarizes multiple contributors to surgical quality (Figure 2; below) and provides guidance for translating complex volume effects to smaller institutions:

*“Volume is a structural component to develop efficiency and quality. The specific capabilities and process characteristics that contribute to surgical outcome improvement should be defined and exported. Adequate focus should allow even small institutions to benefit from volume-associated effects. All volumes-based learning within standardized processes will finally lead to a plateau-ing of quality. Only innovations will then further improve quality. Possessing volume can set the optimal ground for continuous process research, subsequent change, innovation, and optimization, while volume itself appears not to be a quality prerequisite.”*

Huesch (2008) looks at what we know about the presumed source of the volume-outcome association:

*“In summary, generic appeals to a ‘learning curve’ to explain positive volume-outcome relationships obscure the complexity of potential learning effects. Learning effects may embed multiple components and may occur at various locations; knowledge may depreciate and experience may be more or less fungible within an institution. The wide range of empirical findings concerning the nature of learning effects and their duration supports our view that transportation of intellectual goods across discipline boundaries deserves careful attention.”*

**Figure 2: Factors contributing to quality in surgery**  
Adapted from Kraus (2005)

Factor	Details/examples
Case mix	Type, severity, stage of disease for individual patients
	Patient factors: compliance, comorbidity
Surgical procedure itself	Patients appropriately selected
	Perioperative and complication management
	Follow up and long-term therapy
Volume (structural) factors	Surgeon, team, hospital
	Process design
	Degree of specialization
Other structural contributors	Standardization
	Coordination across disciplines
	Teaching status
	Infrastructure/technology availability

## BACKGROUND

VHA's Technology Assessment Advisory Group (TAAG) and Medical-Surgical Service requested that TAP review the structures, processes, and effects of model programs for rural surgery and procedural practice within the US and in other developed nations' health care systems. Explicit as background to this request was the volume-outcome association discussed above and parallel considerations of regionalizing services (Jesse, 2008; quoted on page 1).

TAP already had produced a review of surgical quality indicators for VHA's Surgical Quality Workgroup (Flynn, 2008), so this new review constitutes a logical continuation of ongoing work on various aspects of surgical quality. The result is two separate but closely related reviews from the same time period (2008-09) and together comprising TAP's support of VHA Surgical Service. Since the literatures covered by the two reviews necessarily overlap to some extent, there may be some duplication of material between them.

Exploratory searches for the present review revealed several relatively distinct if not mutually exclusive bodies of research literature relevant to VA rural surgical quality: this overview will be organized in corresponding sections:

- 1. What changes in surgical quality and access are attained by regionalization of services to high-volume providers?**
- 2. What do we know about the etiology of the volume/experience effect?**

## METHODS

### Search strategy

TAP searched Medline via PubMed and Dialog, Embase, Cochrane, and the HTA databases of INAHTA for articles published from 2000 to February, 2009. Search terms were: "surgical quality", "rural surgery", "access", "regionalization", and "hospital or procedure volume".

TAP restricted all searches to adult human patients and English language publications. TAP included search terms to identify existing systematic reviews or meta-analyses published

between 2000 and 2009, along with publications by authors whose work we knew to be critical to quality discussions.

TAP excluded:

- Articles published before 2000;
- Studies of non-surgical interventions or other inaccurately-indexed studies retrieved by searches;
- Single institution case studies or series;
- Studies in pediatric or developing nation populations;
- Narrative reviews; opinion pieces, or other publications lacking primary data;
- Primary studies already included in systematic reviews;
- Where multiple post-2000 studies report on the volume-outcome association for the same procedure, we exclude all but the most recent or largest.

In addition to literature database searches, TAP posted a query to the INAHTA electronic mail response service to elicit information on model rural procedural practice programs in the health care systems represented by INAHTA member agencies and identified Internet sources of information on such programs or any others relevant to our charge. Finally, hand searching reference lists of articles initially retrieved, allowed TAP to identify and retrieve additional full-text publications.

All articles were selected, read, and abstracted by a single reviewer (KF), who prepared this overview.

### **Analytic framework: epidemiologic study cycle**

The progression of epidemiologic studies, or the epidemiologic study cycle, confirming the existence and strength of an observed association between exposure and disease (or intervention and outcome) is both well-documented and relevant to selecting and using evidence as a basis for quality assurance (Ibrahim, 1985; Mausner and Kramer, 1985; Lilienfeld and Stolley, 1994; Muir Gray, 1997): it begins with observational, hypothesis-generating studies such as single case or case series reports, cross-sectional (also known as survey, correlational, or ecological) studies, which ascertain exposure and disease at the same point in time, and then progresses through analytic, hypothesis-testing studies (case-control or cohort, from which relative risk or estimates can be calculated), and culminates in the randomized controlled trial confirming causality. This progression is equally relevant to quality issues in that interventions, processes, or structures used as indicators should have been demonstrated to be effective.

### **Analytic framework: systematic reviews**

Cook (1997) and Mulrow (1997) define systematic reviews: *"Systematic reviews are scientific investigations in themselves, with pre-planned methods and an assembly of original studies as their 'subjects'. They synthesize the results of multiple primary investigations by using strategies that limit bias and random error..."*

The same authors further specify characteristics of systematic reviews and contrast them with traditional narrative reviews: the latter synthesize articles without reporting methods of selection or quality assessment criteria and thus do not qualify as reproducible science.

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Systematic reviews:

- Ask a focused clinical question;
- Conduct a comprehensive search for relevant studies using an explicit search strategy;

- Uniformly apply criteria for inclusion and exclusion of studies;
- Rigorously and critically appraise included studies;
- Provide detailed analyses of the strengths and limitations of included studies.

Systematic reviews can be quantitative (i.e., meta-analytic, applying statistical methods to summarize study results) or qualitative; in either case the inferences or conclusions of the review must follow logically from the evidence presented. The rigor of this approach is illustrated by the place of systematic reviews in evidence grading schemes (Cook, 1995; Guyatt 1995), where they receive the highest level designation.

### **Analytic framework: appraisal of evidence on quality**

Muir Gray (1997) provides an appraisal checklist:

1. Is there good evidence that the intervention used as an indicator of quality is an effective intervention?
2. Are there standards relating to acceptability and safety?
3. Is there clear information about the method used to develop the standards, e.g. are the standards set by taking the cut-off point for the top quartile of several services?
4. Is there only one measure of quality or are there several measures?

## **RESULTS**

Searches for this overview yielded more than one thousand citations, of which 81 appear in the reference list beginning on page 56, and even fewer (72) were sufficiently relevant for abstraction in the Appendix tables as formally “included” studies.

### **Available systematic reviews**

Figure 3 summarizes systematic reviews identified by searches for this project: the majority only tangentially relevant to rural surgery quality. Clearly, systematic review efforts have focused on the volume-outcome association, reflecting the generally more robust state of that body of literature compared to other aspects of rural healthcare. A few reviews addressing additional isolated topics are listed in Section C of Figure 3, none of them specifically quality of rural general surgery.

Appendix Table 1 provides full details for Figure 3 reviews.

**Figure 3: Summary availability of systematic reviews****Notes:**

- Light-shaded row indicates the systematic review providing core information for the volume-outcome association overview; darker shading divides the figure into sections as indicated.
- Quasi-systematic indicates a review meeting only some criteria for systematic status

Reference	Publication years covered	Content
A: Volume-outcome relation: multiple procedures		
Shervin (2007)	1966-2005	Orthopedic procedures
Urbach (2005)	1980-2004	Relation of association to models of funding and delivery in US and Canada
Killeen (2005)	1984-2004	English-language studies for oncological procedures
Halm (2002)	1980-2000: includes Khuri (VHA; 1999) and Dudley (2000); Subsequently published eligible studies in Appendix Table 1 (Section A).	Population-based studies examining the independent relationship between hospital or physician volume and clinical outcomes.
Total	4 systematic reviews for volume-outcome association in multiple procedures, publication years 1980-2004	
B: Volume-outcome: single procedures		
Mastracci (2008)	1994-2006	EVAR of ruptured AAA
Troëning (2008)	Quasi-systematic; not explicitly reported	Elective AAA repair
Wilt (2008)	1980-2007	Hospital or physician volume and radical prostatectomy
Holt (2007b)	“all published data”	AAA repair (elective and emergent)
Holt (2007a)	Not reported	CEA, England
Sundaresan (2007)	1990-2004	Thoracic surgical oncology
Young (2007)	Not reported	Elective open AAA repair
Hoornweg (2007)	1991-2000	Mortality of ruptured AAA with subgroup analyses for hospital volume
Henebiens (2007)	1966-2006	Elective AAA repair
Van Heek (2005)	1994-2004	Pancreatic resection in the Netherlands
Total	10 systematic reviews, one quasi-: volume-outcome association for single procedures, publication years 1980-2008	
Total systematic reviews for the volume-outcome association	13, one quasi-; publication years 1980-2008	
C: Other review topics relevant to rural health		
Vernooij (2007)	1991-2006	Ovarian cancer outcomes by type of hospital
Glazebrook (2006)	Quasi-systematic review: not reported	Education for procedural skills in rural and remote areas
Parsons (2003)	1990-2002	Barriers to implementation of evidence-based practice in rural and remote areas
Gruen (2003)	1966-2002	Cochrane review: specialist outreach clinics in primary care and rural hospital settings
Campbell (1999)	1978-1997 (Not in Halm)	Cancer treatment programs in remote and rural areas
	4 reviews (3 systematic, 1 quasi-): additional rural health topics	

## RESULTS BY TOPIC

### I. Volume-outcome associations and effects of service regionalization

Halm (2002), abstracted in Appendix Table 1, along with subsequently published studies meeting its inclusion criteria (Section A) covers the volume-outcome literature from 1988 to 2000 and serves as the core material for the volume effects component of this TAP overview. Another systematic review, Dudley (2000), covers roughly the same publication years and is included by Halm (2002), as is a comprehensive assessment of the volume-outcome relation for VHA surgery (Khuri, 1999). TAP thus restricts attention to post-2000 primary studies (Section A, Appendix Table 1). However, TAP abstracted Khuri (VHA; 1999) and Dudley (2000) for readers' convenience.

Although more recent research expands attention to outcomes other than mortality and to time frames beyond hospitalization, while occasionally adhering to newer analytic developments (correction for clustering of outcomes or propensity weighting), it does not materially change Halm's 2002 conclusions.

Other potentially explanatory of or confounding factors to the volume-outcome association are under investigation. These include: other structural features of high volume providers, racial differences in outcomes, different care processes according to volume, and differences according to organization/funding of care (Appendix Table 3). The full explanation of the volume effect necessary to translating volume effects among providers remains a work in progress. While most investigators acknowledge probable positive effects of volume-based regionalization on outcomes, the trade-off in access or patient satisfaction is less clear.

*"The challenge for researchers and clinicians is to find out why higher-volume providers have better outcomes. If better outcomes can be traced to differences in structures and processes of care before, during, and after operations, there is a possibility that quality differences between high- and low-volume providers can be substantially reduced, although it is also possible that at least some of these differences are a result of the "practice makes perfect" hypothesis. If processes of care that are strongly related to outcomes can be identified and then implemented in low-volume hospitals, there may not be a need to consider changing referral patterns. However, this is a long, arduous process that has unfortunately received little attention probably because of the paucity of databases equipped to examine process-outcome relationships." Hannan (2002).*

Meredith (2007; figure 4 below) applies to procedure volume criteria for a good quality measure and finds it lacking:

#### **Figure 4: Volume as a quality measure for total joint replacement**

- Adapted from Meredith (2007);
- More recent literature does not change results of criteria application to volume, in this or in other clinical settings

Criterion	Summary of research findings
<b>Valid:</b> Is the measure associated with an important health outcome?	In larger studies with adequate statistical adjustment for patient age and co-morbidities, procedure volume at the surgeon and hospital level has been shown to have a significant association with multiple important health outcomes (mortality, dislocation, infection requiring invasive treatment, medical complications, revision, LOS, functional outcomes, patient satisfaction) for total joint replacement.
<b>Reliable:</b> Do repeated measures give similar results?	Year-to-year variation in hospital volume is unclear, but outcome does not appear to influence volume.
<b>Accessible:</b>	Volume data are easily and inexpensively obtained from multiple state and national

Criterion	Summary of research findings
Are the data easily and inexpensively obtained?	databases.
<b>Actionable:</b> Does the measure lead naturally to changes in the process or structure of care that in turn will yield improved outcomes?	<ul style="list-style-type: none"> <li>Processes definitively explaining the beneficial effects of volume have not been identified.</li> <li>Regionalization is the obvious policy option for increasing volume, but has had inconclusive results (Appendix Table 2), may be associated with access problems for vulnerable populations, and may negatively impact patient satisfaction.</li> </ul>

## CONCLUSIONS AND DISCUSSION

While a great deal has been published on rural health and health care, relatively little of it says anything of great substance and a correspondingly small body of surgery-specific research is relevant here: Figure 3 demonstrates the limited range of topics in rural surgery covered by available systematic reviews, none of which are specific to or particularly enlightening for the concerns underlying this overview.

While they provide insights into the general state of the rural healthcare literature, the reviews themselves are of variable quality, using insufficiently focused questions or selection criteria and potentially biased vote-counting (Grimshaw, 2002) as summarization methods. The single Cochrane review [Gruen (2003): section C of Appendix Table 1] adheres to the usual Cochrane standard of excellence.

Review shortcomings reflect those of the largely descriptive literature which they cover and the few focused rural healthcare research issues that have been systematically addressed in either primary studies or reviews. The volume-outcome association is the obvious exception and is relevant but not confined to rural surgical service decision making.



Birkmeyer (2006) summarizes several approaches to surgical quality improvement from the payer perspective, bringing together elements from volume and CQI discussions above:

**Figure 5: Strategies to improve surgical care**

- Adapted from Birkmeyer (2006)
- “Centers of excellence” includes selective referral based on volume standards (shaded column).
- Pay for performance” indicates financial incentives for compliance with evidence-based guidelines for care.
- Pay for participation” indicates incentives based on data collection and improvement initiatives.
- The three strategies are not necessarily mutually exclusive: an optimal approach to surgical quality could include elements of all.”

Strategy	Centers of excellence	Pay for performance	Pay for participation
Mechanism	Selective contracting and incentives for patients	Rewards for good performance to improve quality at all hospitals	Underwriting clinical outcomes registries and quality improvement activities
What's in it for providers?	<ul style="list-style-type: none"> <li>• Enhanced reputation for HVHs</li> <li>• More patients</li> </ul>	Financial bonus	Satisfaction
Examples	<ul style="list-style-type: none"> <li>• Leapfrog volume standards;</li> <li>• Regionalization studies in Appendix Table 2</li> </ul>	Appropriate use of perioperative care	Quality initiatives: Flynn (2008)
Strengths	<ul style="list-style-type: none"> <li>• Low measurement burden;</li> <li>• Quick and inexpensive implementation;</li> <li>• Amenable to (perhaps over-simplified) public reporting</li> </ul>	“low hanging fruit”: encourages adoption of simple but effective interventions	<ul style="list-style-type: none"> <li>• Acceptance among surgeons;</li> <li>• Greatest potential for identifying and disseminating effective care processes.</li> </ul>
Limitations	<ul style="list-style-type: none"> <li>• Limited measures and data for identification of excellence;</li> <li>• Limited abilities to change referral patterns;</li> <li>• Risks to vulnerable populations</li> </ul>	<ul style="list-style-type: none"> <li>• Limited number of EB processes in surgery;</li> <li>• Risk-adjusted outcomes neither widely available nor readily incentive-responsive.</li> </ul>	<ul style="list-style-type: none"> <li>• Resources to organize and implement;</li> <li>• Not amenable to public reporting</li> </ul>

Other VHA contributors to volume-outcome policy discussions provide final conclusions that continue to reflect current research:

*“Surgeons can also get involved in the clinical science underlying these policy initiatives. As a start, surgeons could help fill in gaps in the volume-outcome literature. Although the volume-outcome literature is extensive, much more research is needed about processes of care responsible for better outcomes at HVHs and about the relative importance of surgeon-versus-hospital factors with various procedures. In addition to assessing the benefits, researchers need to monitor potentially negative effects of volume-based initiatives on access, patient satisfaction, and training programs, to name just a few areas needing future study. By taking the lead in these areas, surgeons can help to ensure that volume standards are implemented in ways that optimize patient benefits while minimizing unintended harms.” Birkmeyer (2001).*

*“... We need to understand more in depth what makes a better surgical program or a better surgeon to be able to make improvements in surgical training, surgical referrals, and surgical outcomes. We also need to be able to improve current surgical practice and translate the technology and the skills to lower-volume institutions and surgeons. Referring most elective colectomies, lobectomies, and gastrectomies to high-volume centers will not improve care for those patients who do not have access to the centers and surgeons with the highest volumes...” Daley (2002).*

To further summarize for individual questions addressed in this review:

## **1. What changes in surgical quality and access are attained by regionalization of services to high volume providers?**

While the existence of a volume or experience effect for a wide range of complex surgical procedures is not seriously contested, its policy implications certainly are. The association remains the subject of ongoing research to refine analytic techniques and to understand the multiple contributors to it, including: complex interactions with other structural features of providers; differential access to care by race; system characteristics such as organization and financing of care; and shifting of patients among alternate procedures.

Much of the volume-outcome research remains single procedure- or condition-specific. In addition, some post 2000 publication dates still report on procedures performed in the previous decade, rendering generalization to a wider range of procedures or current surgical practice problematic. As indicated above and by cross-referencing among Appendix tables, the complexity of volume-outcome research defies simplification to any single simple or intuitive statement.

Thoughtful commentators on the volume-outcome association generally concur in advising careful examination of process or other structural differences among different volume providers as a basis for translating volume effects to smaller providers and enhancing quality at all volume levels. A few examinations have begun to be published, but all are procedure-specific and may not translate to generic national policy.

Only a single modeling study (Holt, 2008; Appendix Table 2) provides evidence directly relevant to VHA interest in the potential effectiveness of a hub-and-spoke structure for surgical services. Holt (2008) used UK data [volume, outcome, and travel time or distance for vascular surgery (elective AAA repair and CEA)] as variables in the model. A similar approach could be used with VHA data for other procedures and geographic areas.

Finally, regionalization evaluations are very limited in scope and scale: while several cross-sectional studies in Appendix Table 2 purport to account for regionalization, only one (McPhee, 2007) explicitly tracks referral patterns over time, and only Canadian studies evaluate explicit policy initiatives rather than the spontaneous multi-factorial referral pattern changes seen in the complex US healthcare system mosaic to date.

## **2. What do we know about the underlying causes of the volume/experience effect?**

To repeat the summary above: Other potentially explanatory or confounding factors to the volume-outcome association, including other structural features of high volume providers, access and outcomes issues for vulnerable populations, different care processes according to volume, and differences according to organization/funding of care (Appendix Table 2) are under exploration.

Some such factors, including hospital teaching or specialization status, may be surrogate measures of volume but have not been analyzed specifically from that perspective. In other words, complete explanation of the volume effect remains a work in progress. Other aspects of rural surgical quality have yet to be explored analytically, and no INAHTA member agencies reported details of rural surgical quality programs from their healthcare systems.

## APPENDIX

**Table 1: Systematic reviews for rural surgery**

**Notes:**

- Light shaded row indicates core evidence (Halm, 2002) for volume-outcome question in this overview
- Darker shaded rows divide table into sections as indicated

Reference	Objectives/methods	Results
<b>A: Volume-outcome: multiple procedures</b>		
Shervin (2007)	<p>To systematically summarize the relationship between hospital or surgeon volume and patient outcomes in <b>orthopedic surgery</b>:</p> <ul style="list-style-type: none"> <li>• Multiple databases, 1966-2005;</li> <li>• Studies comparing outcomes among patients undergoing orthopedic procedures (hip, knee or shoulder arthroplasty; trauma; spine; hand/upper extremity; orthopedic oncology at hospitals or by surgeons with different volumes.</li> <li>• Outcomes considered: mortality; hip dislocation; infection; revision; complications (pulmonary embolus, DVT, functional status, satisfaction).</li> </ul>	<p><b>Results by procedure (26 articles summarized by vote count):</b></p> <ul style="list-style-type: none"> <li>• 8 studies for primary total hip or knee: 3 found associations; 32% reduction in in-hospital deaths for centers with &gt;200 THAs/yr.</li> <li>• 1 study for revision hip or knee: positive association between dislocation and volume;</li> <li>• Combined primary or revision total or partial hip or knee: ¾ studies found positive association with mortality' 1/3 studies of complications found them less likely in low volume centers.</li> <li>• Shoulder: ½ studies found association with mortality; 1 study of revisions found no association;</li> <li>• Hip fracture/trauma: 4/5 studies investigating complications and mortality found associations;</li> <li>• Spinal procedures: 4 studies overall investigated complications or revisions; 4/4 found associations;</li> <li>• General orthopedic procedures: 2/2 found association of mortality with hospital volume;</li> <li>• Surgeon volume: 2/7 found association, mortality-volume after primary total hip or knee; associations with mortality, revision, and satisfaction in small numbers of studies for each outcome.</li> </ul> <p><b>Conclusions:</b> "Overall, we found strong associations between higher hospital volumes and mortality rates (13/22 studies) and hip dislocation rates (2/3). Higher hospital volume was shown to have no effect on lower risks of infection (0/11) or functional outcome (1/4). Furthermore, higher surgeon volume was strongly associated with a lower rate of hip dislocation (3/4). Higher surgeon volume was show to have no effect on functional status (0/3). The data on the effect of hospital and surgeon volume on all other patient outcomes were inconclusive)."</p>
Urbach (2005)	<p>Effect of different models of health care financing and delivery on volume-outcome association: <b>Canada Vs US</b></p>	<p><b>142 articles representing 291 separate analyses:</b></p> <ul style="list-style-type: none"> <li>• 90.1% of articles were US;</li> </ul>

Reference	Objectives/methods	Results
	<p>Medline and Embase (1980-April 2004) plus reference lists:</p> <ul style="list-style-type: none"> <li>• Volume-outcome studies in English;</li> <li>• Excluded: studies done other than US or Canada; those combining data from both; articles without original data; analyses for which there was no Canadian data (CABG, other heart surgery, CEA, PCI, trauma care).</li> <li>• Small cell sizes (AIDS, AMI, obstetric care, miscellaneous conditions) collapsed into a single category</li> </ul>	<ul style="list-style-type: none"> <li>• 1979-2004; 57% post 1997;</li> <li>• Most reported a single analysis, but others 2-17 analyses in one article;</li> <li>• Considerable variation in study population size, countries, numbers of hospitals and individual surgeons, data sources, conditions, and procedures.</li> <li>• Most common conditions and procedures: general surgery (44%); AAA repair (7.9%); PCI (7.2%); CEA (6.9%).</li> <li>• 19 (6.5%) analyses from Canada;</li> <li>• 206 analyses (74.1%) reported statistically significant associations.</li> </ul> <p><b>Country of analysis and likelihood of an association:</b></p> <ul style="list-style-type: none"> <li>• Larger proportion of analyses from US showed a significant association than those from Canada (75.3% Vs. 57.9%);</li> <li>• Some procedures frequently studied in US were never examined in Canada: CEA CABG,/other types of cardiac surgery;</li> </ul> <p><b>Conclusions:</b> <i>“Canadian volume-outcome studies are less likely to identify statistically significant volume-outcome associations than US studies, possibly because of the smaller size of Canadian studies. It is also possible that different models of health care financing and delivery affect patterns of procedure volumes and volume-outcome associations. By promoting competition between hospitals and providers, market-based models may exacerbate existing variations in the quality of hospital care.”</i></p>
Halm (2002)	<p>Medline and Cochrane, 1980-2000:</p> <ul style="list-style-type: none"> <li>• Assessment of relation between volume and outcome in health care;</li> <li>• English language;</li> <li>• hospital or physician volume was independent variable and health outcome was dependent variable;</li> <li>• samples were community or population based;</li> <li>• Patients were treated since 1980;</li> <li>• Excluded: studies from single institutions; voluntary registries or other convenience samples; trauma; newborn intensive care; organ transplant;</li> <li>• Methodologic review focused on key design attributes known to influence validity and generalizability: quality of risk adjustment techniques; control for specific processes of care known to result in better outcomes; explicit measurement of appropriateness of patient selection for procedures; type of outcomes assessed; numbers of hospitals and physicians in each study; number of volume strata assessed; unit of</li> </ul>	<p><b>Methodologic characteristics of included studies:</b></p> <ul style="list-style-type: none"> <li>• 254 articles: 18 reported on &gt; 1 procedure or condition and evaluated as &gt; study (equivalent to 272 studies total).</li> <li>• 135 (53%) met all inclusion criteria and covered 27 clinical topics.</li> <li>• Reasons for exclusion: volume not independent variable (43 studies); not population based (40); data obtained before 1980 (29); no primary health outcomes assessed; mixed outcomes reported; or data duplicative.</li> <li>• Literature extremely heterogeneous, even for a given procedure, making formal meta-analysis impossible.</li> <li>• Countries in which studies conducted: US (124); Canada (6); Europe (3); UK (2);</li> <li>• Half of all studies published since 1998.</li> <li>• Majority based on state or national hospital discharge databases and with sample sizes &gt; 1000, including ≥ 20 hospitals or ≥ 50 physicians.</li> <li>• 79% of studies reported primary outcome as death (usually inpatient); 21% of studies measured additional outcomes to death.</li> <li>• 90% of studies analyzed ≥ 3 volume categories and a few analyzed volume as a continuous variable.</li> </ul>

Reference	Objectives/methods	Results
	analysis; samples of all patients undergoing a specific procedures rather than patients with one type of insurance	<ul style="list-style-type: none"> <li>• 67% analyzed effect of hospital volume only; 8% physician volume only.</li> <li>• 9% of studies examined both hospital and physician volume but failed to explore joint effects.</li> <li>• Only 16% of studies used multivariate analyses designed to separate independent or synergistic effects of hospital and physician volume.</li> </ul> <p><b>Risk adjustment:</b></p> <ul style="list-style-type: none"> <li>• 12% of studies performed no risk adjustment.</li> <li>• 60% used administrative data; 28% used clinical data (but only 7% reported robustly discriminating well-calibrated risk adjustment models);</li> </ul> <p><b>Other rarely addressed methodologic issues:</b></p> <ul style="list-style-type: none"> <li>• Only 2 studies reported appropriateness of patient selection.</li> <li>• 10 studies attempted to account for differential use of key processes of care between high- and low-volume providers.</li> </ul> <p><b>Summary findings of included studies:</b></p> <ul style="list-style-type: none"> <li>• 169 assessments of relationship between hospital or physician volume and outcomes: 118 (70%) found statistically significant association between higher volumes and better outcomes.</li> <li>• No study found a significant association between higher volume and poorer outcome.</li> <li>• The same proportion of studies found significant associations between outcomes and hospital volumes (71%) and outcomes and physician volumes (69%).</li> <li>• 21 studies examined independent effects of both physician and hospital volume: 12 significant effects for both; 4 significant effects for hospital only; 4 significant effects for physician only; 1 no significant effect for either.</li> </ul> <p><b>Relation of risk adjustment method to results (hospital volume):</b></p> <ul style="list-style-type: none"> <li>• No simple relationship found.</li> <li>• <b>Hospital</b> : 4% of articles without risk adjustment reported positive hospital volume-outcome association Vs 82% using administrative data Vs 50% using clinical data (<math>P &lt; 0.001</math>).</li> <li>• <b>physician volume</b>: 62% of studies with no risk adjustment reported positive association Vs 68% of those using administrative data Vs 73% of studies using clinical data (<math>P &gt; 0.02</math>).</li> </ul> <p><b>Conclusions:</b> <i>"High volume is associated with better outcomes across a wide range of procedures and conditions, but the magnitude of the association varies greatly. The clinical and policy significance of these findings is complicated by the methodologic</i></p>

Reference	Objectives/methods	Results
		<i>shortcomings of many studies. Differences in case mix and processes of care between high- and low-volume providers may explain some of the observed relationship between volume and outcome."</i>
Dudley (2000)	<ol style="list-style-type: none"> <li>To determine difference in mortality between high- and low-volume hospitals for conditions for which good quality data exist.</li> <li>To estimate how many deaths potentially could be avoided in CA by referral to high-volume hospitals.</li> </ol> <p><b>Systematic review:</b></p> <ul style="list-style-type: none"> <li>1983-1998;</li> <li>Multiple databases;</li> <li>All articles reporting on the relationship between hospital volume and mortality that used data on procedures performed after 1988 and included &gt; 2 high volume hospitals;</li> <li>Meta-analysis could not be performed, so articles grouped by procedure or diagnosis and single best article selected;</li> <li>Excluded: outcomes other than 30 day mortality; and studies using patient variables not available on CA discharge database.</li> </ul> <p><b>Estimation of avoidable deaths:</b></p> <ul style="list-style-type: none"> <li>OR for in-hospital mortality calculated from single best study identified in review and applied to 1997 California discharges</li> </ul>	<p><b>72 articles addressing 40 procedures and diagnoses:</b></p> <ul style="list-style-type: none"> <li>Mortality significantly lower at HVHs: elective AAA repair; CEA; lower extremity arterial bypass; CABG; coronary angioplasty; heart transplantation; pediatric cardiac surgery; pancreatic and esophageal cancer surgery; cerebral aneurysm surgery; HIV/AIDS treatment.</li> <li>No relation between volume and mortality for emergent AAA repair; knee replacement; AML.</li> </ul> <p><b>121, 609 CA patients in 1997, 58, 306 treated at LVHs:</b></p> <ul style="list-style-type: none"> <li>ORs for mortality at LVHs applied to 1997 patients: 602 deaths (CI, 304-830) at LVHs could be attributable to low volume;</li> <li>None of 128 comparisons showed worse mortality at HVHs, most of which were university centers.</li> <li>Sensitivity analyses using lowest and highest mortality estimates: 513 deaths attributable to low volume, Vs 1042 deaths for highest estimates.</li> </ul> <p><b>Conclusions:</b> "Initiatives to facilitate referral of patients to HVHs have the potential to reduce overall hospital mortality in California for the conditions identified. Additional study is needed to determine the extent to which selective referral is feasible and to examine the potential consequences of such initiatives."</p>
<b>a: Subsequently published primary studies meeting inclusion criteria for Halm (2002; above)</b>		
Brookfield (2009)	See Table 2	
Dimick (2009)	<p><b>Trends in use and outcomes of hepatic resections:</b></p> <ul style="list-style-type: none"> <li>NIS, 1988-2000;</li> <li>HVH<math>\geq</math>10 procedures/yr (&gt; 50<sup>th</sup> percentile);</li> <li>In-hospital mortality adjusted for patient demographics, nature of admission, indication for resection, extent of procedure, LOS.</li> </ul>	<p><b>16,582 resections during study period:</b></p> <ul style="list-style-type: none"> <li>Over study period: significant increase in proportion of procedures performed at HVHs, '88-'89 (37%); '99-2000 (57%; P&lt;0.001);</li> <li>Majority of resections performed at teaching hospitals (57% Vs. 74% P&lt;0.001);</li> <li>Overall in-hospital mortality, 7.4%; varied according to indication and extent of resection: metastatic tumors, 4.2%; primary malignancy, 11.2% (P&lt;0.001); lobe resection, 9.4%; wedge resection, 6.3% (P&lt;0.001);</li> <li>Overall mortality declined significantly over time: '88-'89 10.4%; '99-2000, 5.3% (P&lt;0.001);</li> <li>Multivariate analyses for mortality: 37% (CI, 16-62%) increased risk for 1988-9 Vs</li> </ul>

Reference	Objectives/methods	Results
		<p>later periods.</p> <ul style="list-style-type: none"> <li>Median LOS declined over time: '88-'89, 11 days (8-17); '99-2000, 7 days (6-11).</li> </ul> <p><b>Conclusions:</b> <i>"The number of hepatic resections performed in the US has increased significantly. Short-term outcomes have also improved over the same time period, with more improvement seen at higher volume centers than in lower volume centers."</i></p>
McPhee (2009)	<b>Endovascular repair of ruptured AAA:</b>	
Miyata (2009)	See Table 2	
Dimick (2008)	<p><b>Has introduction of endovascular repair changed volume-outcome association for AAA surgery?</b></p> <ul style="list-style-type: none"> <li>Medicare database, 2001-03;</li> <li>Operative mortality for all AAA repair; and for endovascular Vs. open;</li> <li>Adjustments for patient demographics, acuity, income, comorbid diseases;</li> </ul>	<p><b>80,953 patients during study period:</b></p> <ul style="list-style-type: none"> <li>Endovascular repair in 26,750 (33%);</li> <li>Patients receiving endovascular repair more likely to be male and white;</li> <li>Although most AAA admissions were elective, patients receiving endovascular repair were even more likely elective;</li> <li>During study period, endovascular repair went from 27% to 39% of repairs in Medicare patients (<math>P &lt; .001</math>); for patients 65-75 years: 22% to 33% of total repairs (<math>P &lt; .001</math>);</li> <li>4% of hospitals VHVH, 8% HVH, 7% MVH, 75% LVH;</li> <li>Higher volume hospitals more likely to use endovascular repair: HVH, 44% of the time; LVH, 18%;</li> <li>Strong correlation between total volume and both open volume (Spearman <math>\rho = 0.96</math>; <math>P &lt; .001</math>) and endovascular volume (Spearman <math>\rho = 0.80</math>; <math>P &lt; .001</math>): most HVH and VHVH for total volume were the same for endovascular and open volume</li> <li>Endovascular associated with lower mortality (2.5%) Vs. open repair (6.6% <math>P &lt; .001</math>);</li> <li>Older patients had higher mortality for both types of repair: <math>P &lt; .001</math> for all comparisons; but differences larger for oldest patients 4.5% endovascular, 14.5% open; <math>P &lt; .001</math>) and those undergoing emergency repair</li> <li>Mortality did not change significantly during study period for either type of repair;</li> <li>Strong inverse relationship for total hospital volume and risk-adjusted mortality for all types of repairs: <math>P &lt; .001</math> for all comparisons.</li> </ul> <p><b>Conclusions:</b> <i>"As the endovascular repair becomes more widespread, the relationship between hospital volume and operative mortality still remains. Higher-volume hospitals were more likely to use the endovascular approach, and this explains a significant proportion of the observed impact of hospital volume on mortality."</i></p>

Reference	Objectives/methods	Results
Egorova (2008)	<p><b>Impact of EVAR for ruptured AAA on volume-outcome association:</b></p> <ul style="list-style-type: none"> <li>• Medicare inpatient dataset for 1995-2004;</li> <li>• Annual surgeon and hospital volumes for emergent and elective repair;</li> <li>• Patients match by propensity score to create two cohorts;</li> <li>• Co-morbidities as reported at index hospitalization: cardiac disease (coronary artery and valve; congestive heart failure; arrhythmia); diabetes; hypertension; COPD; clinically significant lower extremity vascular disease; cerebrovascular disease; liver disease; renal atherosclerosis or failure; kidney transplant; neurological disorders; cancer' rheumatoid arthritis;</li> <li>• Treatment selection bias controlled by propensity score;</li> <li>• Regression variables/adjustments: patient demographics ; year of surgery; hospital and surgeon volume in EVAR, OAR, RAAA.</li> </ul>	<p><b>43,033 patients:</b> 41,969 OAR; 1064 EVAR</p> <ul style="list-style-type: none"> <li>• Rates of diabetes, hypertension, other co-morbidities higher in EVAR group;</li> <li>• Evaluation without propensity matching: no statistical advantage for EVAR after 90 days;</li> <li>• Survival with propensity matching: EVAR benefit persisted up to 4 years of FU;</li> <li>• Perio-perative and long-term survival after RAAA correlated with increasing annual surgeon and hospital volume for EVAR and OAR.</li> <li>• EVAR is protective: HR, 0.57 P=.0061.</li> </ul> <p><b>Conclusions:</b> <i>“When EVAR and OAR patients are compared using a reliable statistical technique such as propensity analysis, the perioperative survival advantage of RAAA repaired endovascularly is maintained over the long term. Institutional experience with RAAA is critical for survival after either OAR or EVAR.”</i></p>
Nazarian (2008)	<p><b>To allow 10 years of Maryland state data to drive volume thresholds for CEA:</b></p> <ul style="list-style-type: none"> <li>• Maryland hospital discharge database, 1994-2003;</li> <li>• Annual volume: total number of procedures in database divided by total years;</li> <li>• Non-linear death-volume relationships by random effects with adjustment for clustering and CCI;</li> </ul>	<p><b>22,722 procedures during study period:</b></p> <ul style="list-style-type: none"> <li>• 123 in-hospital deaths (0.54%); crude odds of death for all surgeons, 0.9838: odds decrease by average of 0.0162 for each additional procedure performed;</li> <li>• Surgeon volume of 4-15/yr highly significant for increase by one procedure/yr; estimated odds of death decreased by average of 0.0165 when controlling for hospital volume, age, and comorbidity (P= .351);</li> <li>• Surgeons in other volume categories also showed lower odds of death with increased volume, but changes NS;</li> <li>• Surgeons with <math>\leq 3</math>/yr: OR for death 0.802 per each additional procedure (P = .351);</li> <li>• &gt;15/yr, OR 0.997 (P = .485);</li> <li>• Hospitals &gt;130/yr: OR for death 0.945 for each additional procedure; <math>\leq 130</math>/yr, OR 0.009 for each additional procedure (P = 0.563);</li> </ul> <p><b>Conclusions:</b> <i>“We have demonstrated a technique for rigorous statistical analysis of volume-outcome data and have found a volume effect after CEA in this 10-year Maryland dataset. Higher volume surgeons had lower estimated odd f death, particularly those performing 4 to 15 CEAs per year. These data suggest that a patient undergoing CEA by a surgeon performing 16 CEAs annually has a statistically equivalent risk of death compared with one undergoing CEA by a surgeon with any number higher than this, when controlling for hospital volume, patient comorbidity, and patient age. Hospital volume was not seen to be as significant a predictor of postoperative death in this study,</i></p>



Reference	Objectives/methods	Results
		<i>with only high volume hospitals (<math>\geq 130</math> CEAs per year) showing a statistically significant decrease in the odds ratio of death. As studies on volume-outcome relationships can have important implications for health policy and surgical training, such studies should consider non-linear effects in their modeling of procedural volume."</i>
Manley (2008)	<b>Volume and total hip arthroplasty revision rates:</b> <ul style="list-style-type: none"> <li>Medicare claims data for 1997-2004;</li> <li>Primary and revision total hip arthroplasty;</li> <li>Revision rates and hazard ratios at 0.5, 2, 2, and 8 years; hospital and surgeon volume;</li> <li>Adjustments for patient demographics and hospital characteristics</li> </ul>	<b>26,036 procedures during study period:</b> <ul style="list-style-type: none"> <li>33% at hospitals with &gt; 100/yr;</li> <li>1/6 by surgeons with &gt; 50/yr;</li> <li>Patients treated by high volume surgeons had lower revision rates than low volume surgeons (6-10/yr; adjusted HR, 1.67) or by medium volume surgeons (11-25/yr; HR, 1.63);</li> <li>No effect of surgeon volume at longer FU periods.</li> </ul> <b>Conclusions:</b> <i>"The majority of total hip arthroplasties in the Medicare population from 1997 to 2004 were not performed by the highest-volume hospitals or surgeons. Our findings suggest that patients of low-volume surgeons have a greater risk of arthroplasty revision at six months but no greater risk for revision at the time of longer-term follow-up. There appeared to be no significant association between hospital volume and the rate of revisions of total hip arthroplasties."</i>
McColl (2008)	See Table 2	
Reavis (2008)	<b>Volume-outcome for esophagectomy at academic medical centers:</b> <ul style="list-style-type: none"> <li>UHC clinical database discharges, 2003-2007;</li> <li>Benign and malignant diseases;</li> <li>LOS, 30-day readmission, morbidity, mortality adjusted for severity and complexity of secondary diagnoses;</li> <li>Hospitals volumes: low (<math>\leq 5</math>); medium (6-12); high (&lt; 12)</li> </ul>	<b>5236 procedures during study period:</b> <ul style="list-style-type: none"> <li>30 HVH (3984 procedures) 23 medium (822); 54 LVH (430);</li> <li>HVHs had: shorter LOS (14.1 days Vs 17.2 at LVHs; <math>P &lt; 0.01</math>); fewer overall complications (51.1% Vs 56.6; <math>P = 0.03</math>); pulmonary complications (18.5% Vs 29.8%; <math>P &lt; 0.01</math>); hemorrhagic complications 3.2% Vs 6.7; <math>P &lt; 0.01</math>; (patients requiring skilled nursing facility care (9.5% Vs 19.7%; <math>P &lt; 0.01</math>); lower in-hospital mortality.</li> </ul> <b>Conclusions:</b> <i>"In-hospital mortality was significantly better than expected in hospitals that perform more than 12 cases/year. Hospitals performing a high-volume number of esophagectomies also had a shorter length of stay, lower perioperative morbidity, and decreased need for discharge of patients to skilled/rehab facilities."</i>
Barbieri (2007)	Hospital characteristics associated with <b>radical cystectomy</b> outcomes: <ul style="list-style-type: none"> <li>data from UHC and Vanderbilt University: radical cystectomy for bladder cancer, 2002-05;</li> </ul>	<b>6728 UHC patients ; 421 Vanderbilt (7149 total):</b> <ul style="list-style-type: none"> <li>Vanderbilt: complication rate, 32.07%; mortality, 0.95%; LOS, 7.05 days;</li> <li>UHC: complications, 37.16%; mortality, 1.47%; LOS, 10.98;</li> <li>Institutions with higher cystectomy volumes had significantly better outcomes;</li> </ul>

Reference	Objectives/methods	Results
	<ul style="list-style-type: none"> <li>Outcomes: LOS, complication rates, in-hospital mortality</li> </ul>	<p>mortality with &gt; 50 procedures/yr, 0.54% Vs. 2.70% with &lt; 10 procedures/yr (<math>P &lt; 0.0005</math>;</p> <ul style="list-style-type: none"> <li>Outcomes varied only minimally with total hospital discharges or geographic region.</li> </ul> <p><b>Conclusions:</b> “Even among academic medical center hospitals with a higher volume of cytectomies in 2002-2005 were associated with improved outcomes, including decreased mortality, shorter length of stay and lower rehospitalization rates. These data may provide a framework for self-assessment and help establish criteria for performance evaluation.”</p>
McPhee (2007)	See Table 3	
Eckstein (2007)	<p>131 German hospitals participating in German Society for Vascular Surgery registry for elective open and endovascular repair of AAA:</p> <ul style="list-style-type: none"> <li>Procedures performed 1999-2004;</li> <li>Annual volume as continuous variable;</li> <li>Other variables in logistic regression: patient age, diagnostic tests, AAA diameter, concurrent iliac aneurysm, inflammation, presentation (elective or urgent), ASA score, operative and postoperative variables;</li> </ul>	<p><b>10,163 procedures;</b> predictors of increased peri-operative mortality:</p> <ul style="list-style-type: none"> <li>Age (OR, 1.085; CI, 1.066-1.102);</li> <li>AAA diameter (OR, 1.008; CI, 1.001-1.016);</li> <li>Procedure length (OR, 1.008; CI, 1.006-1.102);</li> <li>ASA score (OR, 2.636; CI, 2.129-3.264);</li> <li>Supra-renal clamping (OR, 1.447; CI, 1.008-2.078);</li> <li>Blood transfusion (OR, 1.786; CI, 1.268-2.514);</li> <li>Annual volume was moderately predictive (OR, 1.003; CI, 1-1.006) but not significant;</li> <li>Operations at low-volume hospitals were longer (<math>P &lt; 0.001</math>) with extended post-operative stays (<math>P &lt; 0.001</math>) and higher transfusion rates (<math>P &lt; 0.001</math>).</li> </ul> <p><b>Conclusions:</b> “Patient’s age, ASA classification, AAA diameter, length of procedure, suprarenal clamping and blood transfusion are predictive variables for increased mortality in elective open AAA repair. Mortality is also increased by low annual volume. Further studies are needed to examine whether these data are applicable to all German hospitals.”</p>
Gutierrez (2007a)	<p><b>Soft tissue sarcoma:</b> prognostic significance of hospital volume;</p> <ul style="list-style-type: none"> <li>Florida cancer registry, 1981-2001;</li> <li>Two volume categories: high (&gt; 67th percentile in ranking by volume) Vs low volume;</li> <li>Cross-sectional: tumor type (fibro-; lipo-; fibrous histio-; leiomyo-); size; anatomic location; patient demographics; adjuvant therapy</li> <li>30- and 60- day mortality; amputation rate.</li> </ul>	<p><b>4205 procedures:</b></p> <ul style="list-style-type: none"> <li>68.1% at low volume centers, 31.9% at high volume;</li> <li>High volume centers treated larger percentages of patients with high grade and large tumors: 53.8% vs. 44.3% (<math>P &lt; 0.001</math>); and 40.7% Vs. 28.7% (<math>P &lt; 0.001</math>) respectively;</li> <li>90 day mortality: high volume 1.6% Vs low 3.6% (<math>P &lt; 0.001</math>);</li> <li>Median survival: high, 40 months, low 37 (<math>P = 0.001</math>);</li> <li>Univariate analyses: significantly improved survival at high volume centers for high grade tumors (30 Vs 24 months; <math>P = 0.001</math>); tumors &gt; 10 cm (28 Vs. 24 months; <math>P = 0.001</math>); and truncal or retroperitoneal location (39 Vs 31 months; <math>P = 0.011</math>);</li> </ul>

Reference	Objectives/methods	Results
		<ul style="list-style-type: none"> <li>Limb amputation lower at high volume (9.4% Vs. 13.8%; P=0.048) and adjuvant therapy more frequent (OR, 1.54);</li> <li>Multivariate analyses: treatment at high volume center significant independent predictor of improved survival: (RR, 1.292; P=0.047).</li> </ul> <p><b>Conclusions:</b> “<i>STS patients treated at HVC have significantly better survival and functional outcomes. Patients with either large (&gt; 10 cm), high-grade or truncal/retroperitoneal tumors should be treated exclusively at a high-volume center</i>”</p>
Burton (2006)	<p><b>Peri-procedural and medium-term adverse events after PCI:</b></p> <ul style="list-style-type: none"> <li>Scottish Coronary Revascularization Register and Morbidity records, 1997-2003;</li> <li>Risk of events by hospital volume at 30 days and 2 years;</li> <li>LVH (&lt;400); MVH (400-750); H VH (&gt;750);</li> <li>Outcomes: all-cause death; fatal or nonfatal MI; repeat PCI; CABG; any revascularization (repeat PCI or CABG);</li> <li></li> </ul>	<p><b>17,417 procedures during study period:</b></p> <ul style="list-style-type: none"> <li>4900 (28%) in LVHs; 3242(19% ) in HVHs;</li> <li>After adjustment for case mix: no significant differences in risks for death or MI;</li> <li>Patients at HVHs less likely to require emergency surgery (OR, 0.18; CI, 0.097-0.54; p = 0.002).</li> <li>At 2 yrs: Patients at HVHs less likely to undergo surgery (HR, 0.52; I, 0.35-0.75; p = 0.001), but this was offset by increased likelihood of further PCI ;</li> <li>No net difference in coronary revascularization or overall events.</li> </ul> <p><b>Conclusions:</b> “<i>Death and myocardial infarction were infrequent complications of PCI and did not differ significantly by volume. Emergency surgery was less common in high-volume hospitals. Over two years, patients treated in high-volume centres were as likely to undergo some form of revascularization but less likely to undergo surgery.</i>”</p>
SooHoo (2006)	<p><b>Primary total knee arthroplasty:</b></p> <ul style="list-style-type: none"> <li>California admissions and death records, 1991-2001;</li> <li>Hospital volume Vs complications;</li> <li>Adjusted for patient demographics, insurance type, CCI, hospital type/size, year of procedure, uni- or bilateral.</li> </ul>	<p><b>222,684 primary total knee arthroplasty procedures:</b> Patients at LVHs had greater likelihood within 90 days of discharge:</p> <ul style="list-style-type: none"> <li>death (0.55% Vs. 0.49%; OR, 1.50; CI, 1.14-1.98; P = .004);</li> <li>readmission for infection (1.13% Vs. 0.65%; OR, 1.60; CI, 1.21-2.12I P = .001);</li> <li>pulmonary embolism (0.48% Vs. 0.39%; OR, 1.54; CI, 1.07-1.97; P = 0.016);</li> <li>thrombophlebitis (0.49% Vs 0.28; OR, 2.12; CI, 1.47-3.05; P&lt;.001).</li> <li>Surgeries earlier in study period significantly more likely ORs for complications in first 90 days;</li> <li>Higher ORs for increasing age and higher CCI;</li> <li>Bilateral procedures: significantly higher ORs for pulmonary embolism and mortality but not infection or thrombophlebitis at 90 days;</li> <li>Black race: higher OR for pulmonary embolism at 90 days, but not for other outcomes;</li> <li>No consistent pattern for insurance type hospital size independent of volume, or teaching status;</li> </ul>

Reference	Objectives/methods	Results
		<p><b>Conclusions:</b> <i>"This study confirms an association between hospital surgical volume and certain outcomes after primary total knee arthroplasty...Despite this relationship, this study also shows that the absolute rates of complications and readmission remain low even at low volume centers. Given these findings as well as the pattern of use in this population, regionalization to high volume centers may not be feasible or necessary for total knee arthroplasty."</i></p>
Birkmeyer (2005)	Appendix Table 2, Section A	
Carey (2005)	<p>PCI and CABG:</p> <ul style="list-style-type: none"> <li>New York and California, 1999-2001 state databases;</li> <li>Risk-adjusted (demographic factors and co-morbidities) in-hospital mortality;</li> </ul>	<ul style="list-style-type: none"> <li>CABG mortality 33% higher in CA versus NY;</li> <li>PCI mortality twice in CA Vs NY;</li> <li>Procedure rate/unit population twice in NY Vs CA;</li> <li>High volume CA hospitals (&gt; 300 procedures/yr) had similar CABG mortality to NY (2.43% Vs. 2.25%);</li> <li>Excess CABG mortality (&gt; 4.0%) occurred only in low volume programs;</li> <li>Risk adjust did not change volume effect for CABG;</li> <li>No volume effect for risk-adjusted PCI;</li> <li>No obvious differences in risk factors between the states;</li> <li>Programs performing relatively fewer CABG compared to PCI had significantly higher CABG mortality after adjusting for volume effects;</li> <li>PCI volume is increasing and CABG decreasing in both states.</li> </ul> <p><b>Conclusions:</b> <i>"Excess coronary artery bypass grafting mortality in California is related to the larger number of low-volume programs. Excess percutaneous coronary intervention mortality might be related to case selection or timing of intervention. A relationship between percutaneous coronary intervention volume and coronary artery bypass grafting volume is suggested in which increasing percutaneous intervention volume relative to coronary artery bypass grafting volume might have the effect of shifting patients with undefined higher risk characteristics to coronary artery bypass grafting."</i></p>
Harling (2005)	<p>Colorectal cancer in Denmark, 1994-'99:</p> <ul style="list-style-type: none"> <li>National registry: patients with first-time rectal cancer;</li> <li>Influence of case volume on choice of resection procedure; complications; 30-day and 5-year mortality</li> </ul>	<p><b>5021 patients</b>, September 1994 - August 1999:</p> <ul style="list-style-type: none"> <li>TME introduced in Denmark, 1996; pre-operative radiotherapy for mobile tumors, 2002;</li> <li>Comorbidity, identity, and specialty of surgeon recording in register only later</li> <li>27 hospitals with &lt; 15 procedures/yr; 15 hospitals with 15-30/yr; 11 hospitals with &gt; 30/yr;</li> <li>Multivariate analysis; risk of permanent colostomy significantly increased in low</li> </ul>

Reference	Objectives/methods	Results
		<p>volume hospitals, but volume did not decrease risk of anastomotic leak, 30- day mortality, or 5-yr mortality.</p> <p><b>Conclusions:</b> <i>“in this study, only risk of having a permanent colostomy during surgery for rectal cancer was significantly related to hospital volume. When individual hospitals were analyzed, a large variation in 5-year mortality was observed within the low-volume group of hospitals”</i></p>
Dimick (2004a)	<p><b>Aortic surgery in patients &gt; 65 years:</b></p> <ul style="list-style-type: none"> <li>• Maryland state discharge database, 1994-1996;</li> <li>• 9 patients&lt; 30 years excluded;</li> <li>• Procedures: resection of abdominal aorta with replacement; aorto-iliac/femoral bypass;</li> <li>• Adjusted for: demographics, nature of admission, vital status at discharge, LOS, hospital charges, operating physician, comorbid conditions.</li> </ul>	<p><b>Total 2,987 patients during study period:</b></p> <ul style="list-style-type: none"> <li>• 2,067 (69%)&gt; 65; 920 (31%)&lt; 65;</li> <li>• Patients&gt; 65 more likely to have AAA repair rather than aorto-femoral bypass (73% Vs 37%); emergent admission (24% Vs. 18%); and higher rates of comorbid disease: dementia (1% Vs. 0.1%), COPD (12%; 8%), malignancy (6%; 1%);</li> <li>• Hospital mortality, 7.0% overall (&lt; 65, 2.5%; &gt; 65, 9.4%);</li> <li>• Mortality in patients&gt; 65 by hospital volume: LVH, 11.9%; MVH, 9.9%; HVH, 6.9%;</li> <li>• Independent risks for mortality: hospital volume; mild liver disease, chronic renal disease; AAA; ruptured AAA.</li> </ul> <p><b>Conclusions:</b> <i>“...hospital volume was associated with decreased in-hospital mortality after abdominal aortic surgery only for patients greater than 65 years old. Because of this differential effect, targeting elderly patients for regionalization would achieve most potentially avoidable deaths for this common high-risk surgical procedure.”</i></p>
Epstein (2004)	<p><b>Hospital PCI volume</b> and mortality, 1998-2000: Do ACC/AHA volume minimums (400 PCI/yr) reflect current practice?</p> <ul style="list-style-type: none"> <li>• AHRQ Nationwide In-patient Sample hospital discharge database, 1997-2000 data pooled</li> <li>• Hospitalizations for which patients had primary or secondary PCI code: (362,928 patients &gt; 18 years with data for gender and mortality during hospitalization);</li> <li>• 180 patients treated at hospitals with &lt; 5 PCI coded in any years excluded = final study cohort of 362,748 admissions at 457 hospitals;</li> <li>• Low volume hospitals, 5-199 PCI/yr; medium, 200-399/yr; high, 400-999/yr; very high, &gt;1000/yr.</li> <li>• Patient characteristics: demographics, admission type, comorbidities, payer.</li> </ul>	<p><b>Mortality:</b></p> <ul style="list-style-type: none"> <li>• Crude: 2.56% in low volume; 1.83% in medium; 1.64% in high; 1.35% in very high volume hospitals (p&lt;0.001 for trend);</li> <li>• Compared with patients treated in high volume hospitals (OR=1), patients treated in low volume hospitals had increased risk for mortality (adjusted for patient characteristics), OR 1.21; (CI, 1.06-1.28); medium volume, OR 1.2 (CI, 0.92—1.14); very high volume, OR 0.94 (CI, 0.85-1/0.03); findings similar when high and very high volume hospitals were pooled.</li> </ul> <p><b>Conclusions:</b> <i>“We found no evidence of higher in-hospital mortality in patients undergoing PCI at medium-volume hospitals compared with patients treated at hospitals with annual PCI volumes of 400 cases or more, suggesting current ACC/AHA PCI hospital volume minimums may merit reevaluation.”</i></p>

Reference	Objectives/methods	Results
Katz (2004)	<b>Total knee replacement:</b> <ul style="list-style-type: none"> <li>Medicare claims data for elective procedures, Jan-Aug 2000;</li> <li>90 day mortality and complications (infection, pulmonary embolus, myocardial infarction, pneumonia)</li> <li>Adjusted for: demographics, comorbid conditions, Medicaid eligibility, arthritis diagnosis;</li> <li>Analyses of hospital volume adjusted for surgeon volume and vice versa.</li> </ul>	<b>80,904 patients during study period:</b> <ul style="list-style-type: none"> <li><b>Patient outcomes:</b> 0.6% died; 0.8% AMI; 0.8% pulmonary embolus; 0.4% deep wound infection; 1.4% hospitalized for pneumonia;</li> <li><b>Provider volume:</b> 11% of procedures performed by hospital/surgeons with <math>\leq 25</math> yr; <math>25\% \leq 12</math> procedures;</li> <li>Compared with patients managed by LVHs, those managed by HVHs (<math>&lt; 200</math>/yr): lower risk of pneumonia OR, .065; CI, 0.47-0.90); and any adverse outcome (OR, 0.74; CI, 0.60-0.90);</li> <li>Patients treated by surgeons with <math>&gt; 50</math> procedures/yr compared to <math>\leq 12</math>/yr: Lower risk of pneumonia (OR, 0.72; CI, 0.54-0.95) and any adverse outcome (POR, 0.80; CI, 0.68-0.98).</li> </ul> <p><b>Conclusions:</b> "Patients managed at hospitals and by surgeons with greater volumes of total knee replacement have lower risks of peri-operative adverse events following primary total knee replacement. Patients and clinicians should incorporate these findings into discussions about selecting a surgeon and a hospital for total knee replacement. These data should also be integrated into the policy debate about the advantages and drawbacks of regionalizing total joint replacement to high-volume centers."</p>
Nguyen (2004)	<b>Bariatric surgery:</b> <ul style="list-style-type: none"> <li>UHC administrative, clinical, and financial database;</li> <li>Roux-en-Y gastric bypass for morbid obesity;</li> <li>1999-2002;</li> <li>22 high volume hospitals (13,810 procedures: <math>&gt; 100</math>/yr);</li> <li>27 medium volume (7,634 procedures: 50-100/yr);</li> <li>44 low volume (2722 procedures; <math>&lt; 50</math>/yr)</li> </ul>	<p>Patients at high-volume hospitals compared to low-volume:</p> <ul style="list-style-type: none"> <li>Shorter LOS: 3.8 days Vs 5.1, <math>P &lt; 0.01</math>;</li> <li>Lower overall complications: 10.2% Vs 14.5%, <math>P &lt; 0.01</math>;</li> <li>Lower complications of medical care: 7.8% Vs 10.8%, <math>P &lt; 0.01</math>;</li> <li>Lower costs: \$10,292 Vs \$13,908, <math>p &lt; 0.01</math>;</li> <li>Expected mortality rates similar: 0.6% Vs 0.6%, so patients were similar;</li> <li>Observed mortality: 0.3% Vs 1.2%, <math>P &lt; 0.01</math>;</li> <li>Subset <math>&gt; 55</math> yrs: observed mortality 0.9% (high-volume) Vs. 3.1%, <math>P &lt; 0.01</math>.</li> </ul> <p><b>Conclusions:</b> "Bariatric surgery performed at hospitals with more than 100 cases annually is associated with lower morbidity and mortality, and decreased costs. This volume-outcome relationship is even more pronounced for a subset of patients older than 55 years, for whom in-hospital mortality was 3-fold higher at low-volume compared with high-volume hospitals. High-volume hospitals also have a lower rate of overall postoperative and medical care complications, which may be related in part to formalization of the structures and processes of care."</p>
Peterson (2004)	<b>Hospital volume and operative mortality in CABG:</b>	<b>267,098 CABG procedures during study period:</b>

Reference	Objectives/methods	Results
	<ul style="list-style-type: none"> <li>• STS database, 2000-2001;</li> <li>• All-cause operative mortality (in-hospital or 30-day);</li> <li>• Major morbidity: stroke, re-operation, &gt; 24 hrs mechanical ventilation, renal failure, deep wound infection;</li> <li>• CABG procedures, excluding those combined with valve or other major surgical interventions;</li> <li>• Volume analyzed as continuous variable averaged over two years: ≤151; 151-300; 301-450; &gt; 450;</li> <li>• 12 centers reporting &lt; 30 CABG/yr and with evidence of incomplete reporting excluded; inclusion of those 233 cases did not change results;</li> <li>• Adjustments for patient risks and clustering</li> </ul>	<ul style="list-style-type: none"> <li>• 439 hospitals, 82% performing &lt; 500 procedures;</li> <li>• Median hospital volume, 253 (interquartile range, 165-417);</li> <li>• Rates of mortality decreased with increasing hospital volume: 0.07% for every additional 100 procedures; OR, 0.98 (CI, 0.96-0.99; P = .004);</li> <li>• Association between volume and mortality significant overall, but not observed in patients &lt; 65 or with low operative risk, and confounded by surgeon volume;</li> <li>• Ability of hospital volume to discriminate centers with significantly better or worse outcome limited due to wide variability in risk-adjusted mortality among hospitals with similar volumes;</li> <li>• Closure of up to 100 of lowest volume centers (≤150 procedures/yr) would avert fewer than 50 of 7110 (&lt; 1%) CABG-related deaths.</li> </ul> <p><b>Conclusions:</b> <i>“In contemporary practice, hospital procedure volume is only modestly associated with CABG outcomes and therefore may not be an adequate quality measure for CABG surgery.”</i></p>
Zacharias (2004)	See Table 3	
Taub (2004)	<p><b>Hospital volume effects (mortality and LOS) for patients undergoing nephrectomy for cancer:</b></p> <ul style="list-style-type: none"> <li>• NIS, 1993-97;</li> <li>• Volume groups based on annual nephrectomy rates: LVH (1-14); MVH (15-33); HVH (&gt;33);</li> <li>• Unadjusted and risk-adjusted (for demographics, nature of admission, comorbidities)</li> </ul>	<p><b>20,765 patients in 962 hospitals:</b></p> <ul style="list-style-type: none"> <li>• 80 HVH (8.3%); 165 MVH (17.2%); 717 LVH (74.5%);</li> <li>• 29.4% of patients treated at HVH; 34.2% MVH; 36.3% LVH;</li> <li>• More procedures At LVH (P&lt;0.001); more partial resections at HVH (P&lt; 0.001); but proportions of radical resections similar;</li> <li>• Overall in-hospital mortality 1.39% for all types of nephrectomy during study period;</li> <li>• Statistically significant associations; surgical volume and decreased mortality (overall and partial resection); NS in radical nephrectomy and nephroureterectomy;</li> <li>• Multivariate analyses adjusting for case mix: hospital volume significant: HVH Vs MVH, 32% lower mortality risk (OR, 1.46; CI, 0.95-1.86); HVH Vs LVH, 25% (OR, 1.33; CI, 0.95-1.86);</li> <li>• Other independent predictors of in-hospital mortality: urgent admission (OR, 2.66; CI, 2.07-3.42); age &gt;65 (OR, 3.66; CI, 2.70-4.98); chronic pulmonary disease (OR, 1.59; CI 1/13-2.25); metastatic disease (OR, 2.09; CI, 1.54-2.84);</li> <li>• Overall LOS during study period: 7.80 days; did not differ by hospital volume or case mix;</li> <li>• Independent risks for increased LOS: age &gt; 65 (OR, 1.93; CI, 1.79-2.08); female (OR, 1.09; CI, 1.02-1.18); urgent admission (OR, 5.12; CI, 4.47-5.53); chronic pulmonary disease (OR, 1.48; CI, 1.31-1.67); metastatic disease (OR, 2.17; CI, 21.96-2.41); chronic renal insufficiency (OR, 2.74; CI, 1.52-4.92).</li> </ul>

Reference	Objectives/methods	Results
		<b>Conclusions:</b> <i>'A greater surgical volume, age younger than 65 years, elective conditions, and less comorbidity are associated with a significantly decreased risk of in-hospital mortality after nephrectomy. These findings provide compelling evidence that hospital volume and patient characteristics have important effects on surgical outcome specific to renal neoplasms.'</i>
Dimick (2003)	<b>Colorectal cancer in elderly patients:</b> <ul style="list-style-type: none"> <li>NIS, 1997: resections for colorectal cancer</li> <li>Risk-adjusted mortality with increasing age by quartiles of hospital volume: low volume, &lt;55/yr; medium, 55-100; high, 101-150; very high, &gt; 150;</li> <li>In-hospital mortality adjusted for demographics, 10 comorbid diseases, nature of admission, type of resection</li> </ul>	<b>842 hospitals in 22 states:</b> <ul style="list-style-type: none"> <li>65% of hospitals low volume, 18% medium, 12% high, 7% very high;</li> <li>Very high volume more likely to be teaching (55% Vs 6%; P&lt;0.001); and large bed size (78% Vs. 14%; P&lt;0.001);</li> </ul> <b>20,862 patients:</b> <ul style="list-style-type: none"> <li>Approx one fourth in each volume group, with age and gender similar across groups;</li> <li>Small differences among volume groups: nonwhite race, number of comorbid conditions, median annual income;</li> <li>Patients at LVHs more likely to have no comorbid conditions (33% Vs. 26%); less likely to have &gt; 3 conditions (15% Vs. 18%; P = 0.001) than those in very high volume hospitals;</li> <li>Overall mortality, 3.1%;</li> <li>Increasing age associated with higher in-hospital mortality: &lt; 50, 0.8%; 51-65, 1.3%; 66-80, 2.9%; &gt; 80, 6.9%;</li> <li>Mortality varied with anatomical cancer site and procedure: rectum (2.4%); left colon (4.5%);abdominoperineal resection (2.3%); total abdominal colectomy (6.3%);</li> <li>Hospital volume significantly associated with mortality: VHVH (2.5%) Vs. LVH (3.7%); P = 0.006;</li> <li>Effect of volume on mortality primarily due to differences in patients: &gt; 65: 3.1% at VHVH, 4.5% at LVH; P= 0.03);</li> <li>RR of mortality at VHVH Vs LH variable and had no specific relation to increasing age.</li> </ul> <b>Conclusions:</b> <i>"The majority of deaths after surgery for colorectal cancer occur in older patients. Hospitals that perform higher volumes of colorectal resection have lower mortality rates, especially for older patients. In the absence of other information about the quality of surgical care, provider volumes are a useful marker of postoperative outcomes for older patients in need of surgery for colorectal cancer."</i>
Elixhauser (2003)	See Table 3	



Reference	Objectives/methods	Results
Finlayson (2003)	See Table 2	
Katz (2003)	<p><b>Total hip replacement:</b></p> <ul style="list-style-type: none"> <li>• Stratified random sample: Medicare beneficiaries undergoing elective primary or revision THR;</li> <li>• Ohio, Pennsylvania, Colorado in 1995;</li> <li>• Outcomes (3 yrs): self-reported Harris hip score; validated satisfaction scale;</li> <li>• HVH&gt;100 (primary + revision); LVH≤12 primary procedures or ≤30 revisions.</li> <li>• Adjusted for: socio-demographics; CCI; operative characteristics; history of other orthopedic procedures; complexity of revisions.</li> </ul>	<p><b>Cohort of 1,939 from among 7,092 Medicare procedures during study period:</b></p> <ul style="list-style-type: none"> <li>• Analyses based on THRs in 958 patients and RHRs in 1,568; yielding total 595 patients with complete information and FU;</li> </ul> <p><b>Unadjusted analyses:</b></p> <ul style="list-style-type: none"> <li>• patients at LVHs had worse functional status at 3 years;</li> <li>• Patients with revisions by low volume surgeons had worse function;</li> </ul> <p><b>Adjustment for socio-demographic and clinical variables:</b></p> <ul style="list-style-type: none"> <li>• Association between higher volume and better functional outcome after THR was weak and NS;</li> <li>• No significant association between volume and outcome of revision observed;</li> <li>• Patients undergoing THR at LVHs more likely to be dissatisfied;</li> <li>• Patients having revisions by low volume surgeons more likely to be dissatisfied.</li> </ul> <p><b>Conclusions:</b> "Hospital volume and surgeon volume have little effect on 3-year functional outcome following THR, after adjusting for patient sociodemographic and select clinical characteristics. However, satisfaction with primary THR is greater among patients who underwent surgery in high-volume centers, and satisfaction with revisions is greater among patients whose operations were performed by higher-volume surgeons. Referring clinicians should incorporate these findings into their discussion of referral choices with patients considering THR. <i>"Conclusions regarding the effect of volume on longevity of the implants must await longer-term follow-up studies. Finally, further research is warranted to better understand the association between hospital and surgeon procedure volume and patient satisfaction with surgery."</i></p>
Long (2003)	See Table 3	
Birkmeyer (2002)	<p><b>Mortality associated with cardiovascular and cancer procedures in Medicare population:</b></p> <ul style="list-style-type: none"> <li>• National Medicare claims database, 1994-1999;</li> <li>• Logistic regression with adjustment for age, sex, race, and interactions; year and urgency of procedure; co-existing conditions; mean income from Social Security (zip code from 1990 census);</li> <li>• CABG;</li> <li>• Aortic or mitral valve replacement;</li> <li>• CEA;</li> </ul>	<p><b>2.5 million procedures:</b></p> <ul style="list-style-type: none"> <li>• Mortality decreased as volume increased for all procedures, but relative importance of volume varied markedly according to type of procedure.</li> <li>• Absolute difference in adjusted mortality, very high Vs very low volume: pancreatic resection, 12%; CEA, 0.2%; esophagectomy and lung resection, 5%; gastrectomy, cystectomy, AAA repair, 2-5%; CABG, lower extremity bypass, colectomy, lobectomy, nephrectomy, &lt; 2%.</li> </ul> <p><b>Conclusions:</b> <i>"In the absence of other information about the quality of surgery at the hospitals near them, Medicare patients undergoing selected cardiovascular procedures</i></p>

Reference	Objectives/methods	Results
	<ul style="list-style-type: none"> <li>• Lower extremity bypass;</li> <li>• Elective AAA repair;</li> <li>• Colectomy;</li> <li>• Gastrectomy;</li> <li>• Esophagectomy;</li> <li>• Pancreatic resection;</li> <li>• Nephrectomy;</li> <li>• Cystectomy;</li> <li>• Pulmonary resection</li> </ul>	<p><i>can significantly reduce their risk of operative death by selecting a high-volume hospital."</i></p>
Hannan (2002)	<p><b>Volume-mortality relationship for 3 groups of cancer procedures:</b></p> <ul style="list-style-type: none"> <li>• Colectomy, lung lobectomy, gastrectomy;</li> <li>• NY statewide planning and research cooperative database (acute care hospital discharges) for 1994-'97;</li> <li>• In-hospital mortality by hospital or surgeon volume adjusted for patient age, other demographics, organ metastasis, socioeconomic status, and co-morbidities.</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Hospital volume (gastrectomy):</b> highest volume quartile has absolute adjusted mortality 7.1% lower than lowest volume quartile (<math>P &lt; .0001</math>);</li> <li>• <b>Overall mortality for gastrectomy:</b> 6.2%;</li> <li>• <b>Surgeon volume (colectomy):</b> highest Vs lowest quartiles, 1.9%, <math>P &lt; .0001</math>;</li> <li>• <b>Overall mortality for colectomy, 3.5%;</b></li> <li>• <b>Hospital volume (lung lobectomy):</b> absolute difference, 1.7%;</li> <li>• <b>High-volume surgeons in high-volume hospitals:</b> significantly lower mortality than patients with low-volume surgeons or low-volume hospitals or both.</li> </ul> <p><b>Conclusions:</b> "For all 3 procedure groups, the risk-adjusted mortality is significantly lower when the procedures are performed by high-volume providers."</p>
Khuri (1999)	<p>Included by Halm (2002) but abstracted here as VA-specific research:</p> <ul style="list-style-type: none"> <li>• To determine VHA volume-outcome relation in 8 commonly performed intermediate complexity procedures (vascular infra-inguinal reconstruction; CEA; lung resection open and laparoscopic cholecystectomy; partial colectomy; total hip arthroplasty);</li> <li>• VHA NSQIP data from 44 VAMCs, Dec 1991-Dec 1993;</li> </ul>	<p><b>63,631 procedures in 123 VAMCs (1999):</b></p> <ul style="list-style-type: none"> <li>• Total volume range: 3767 (AAA repair) - 13,310 (partial colectomy);</li> <li>• Mean age range: 57.9 (laparoscopic cholecystectomy) – 68.8 (AAA repair);</li> <li>• female: 0.6% (AAA repair) - 9.1% (laparoscopic cholecystectomy);</li> <li>• emergent cases: 0.6% (pulmonary resection) -18.6% (partial colectomy);</li> <li>• observed 30-day mortality: 0.5% (laparoscopic cholecystectomy)-6.9% (partial colectomy);</li> <li>• Exclusion from analyses: nurse reviewers on leave at time of operation;</li> <li>• Hospitals performing procedures: 93 (CEA)-125 (partial colectomy);</li> <li>• No statistically significant association between procedure or specialty volume and 30-day mortality or stroke rate (CEA).</li> </ul> <p><b>Conclusions:</b> <i>In VHA hospitals, the procedure and surgical specialty volume in eight prevalent operations of intermediate complexity are not associated with risk-adjusted 30-day mortality from these operations, or with the risk-adjusted 30-day stroke rate from CEA. Volume of surgery in these operations should not be used as a surrogate for quality of surgical care."</i></p>

Reference	Objectives/methods	Results
<b>B: Other systematic reviews: volume-outcome in single procedures</b>		
Mastracci (2008)	<p>Systematic review summarizing studies of patients undergoing <b>EVAR for ruptured AAA</b>:</p> <ul style="list-style-type: none"> <li>• heterogeneity analysis for surgical team volume;</li> <li>• multiple databases, 1994-2006 plus reference lists;</li> <li>• English-language studies describing mortality in groups or subgroups of patients with infra-renal ruptured AAA in whom EVAR was attempted.</li> <li>• Excluded: series with &lt; 10 patients; articles duplicating patients with others.</li> <li>• Established quality assessment criteria for non-randomized trials: controls adequately described; direction of inquiry; blinding of outcome assessors; use of algorithm for assessing patient eligibility; disclosure of source of funding</li> </ul>	<p><b>After removal of duplicate citations, searches yielded 3070 citations:</b></p> <ul style="list-style-type: none"> <li>• 114 articles represented 18 independent cohorts of &gt; 10 patients;</li> <li>• 7 studies did not describe the concurrent control; 3 used historical controls, one used patients with symptomatic AAA one other used a concurrent control of anatomically unsuitable or hemodynamically unstable patients EVAR-ineligible patients; two final studies used concurrent controls excluded for other reasons; no study used concurrent controls eligible for EVAR who had open repair</li> <li>• 8 studies were retrospective, 9 prospective, and one did not report direction of enquiry;</li> <li>• 9 studies reported blinding of outcome assessors, and 9 pre-specified outcomes.</li> <li>• Funding sources reported in 14 studies, and 14 reported algorithms for patient selection.</li> </ul> <p><b>Mortality (18 observational studies with 436 patients included in review):</b></p> <ul style="list-style-type: none"> <li>• In-hospital mortality after EVAR, 0-45% (CI, 23-67);</li> <li>• Pooled mortality, 21% (CI, 13-29) with high heterogeneity (<math>I^2</math>), 90.2%;</li> </ul> <p><b>Sensitivity analyses:</b></p> <ul style="list-style-type: none"> <li>• Mortality in prospective studies, 23% (CI, 15-31); VS retrospective, 19% (CI, 7-30);</li> <li>• 14 studies including details of selection algorithm: mortality, 18% (CI, 10-26) Vs no use of algorithm, 32% (CI, 10-28);</li> <li>• Surgical volume &gt; 30 cases, 19% (CI, 10-28); Vs &lt; 30, 22% (CI, 12-33).</li> </ul> <p><b>Conclusions:</b> <i>“Mortality in people who underwent EVAR is lower than that in historical reports of unselected people undergoing open repair. Further investigation is needed to determine whether the difference in mortality is attributable to patient selection alone or to this new approach to treatment.”</i></p>
Troenig (2008)	<p><b>Quasi-systematic review:</b> elective AAA repair:</p> <ul style="list-style-type: none"> <li>• PubMed searched Jan 2008;</li> <li>• Selection criteria: Publication within 10 years; original data on hospital volume (US, Canada, or Europe) volume-outcome association; studies of other independent variables</li> <li>• Excluded: duplicate publications; meta-analyses including older studies;</li> </ul>	<p><b>15 papers:</b></p> <ul style="list-style-type: none"> <li>• Only one focused on threshold value to identify minimum acceptable case load;</li> <li>• Most studies demonstrated significant inverse volume-outcome relation but heterogeneity of study designs precluded pooling of results: 3 studies used volume as continuous variable; remainder used different approaches to volume categories;</li> <li>• US studies: administrative databases with various methods of risk adjustment or control only for demographics;</li> </ul>

Reference	Objectives/methods	Results
		<p><b>Conclusions:</b> “Recent studies from North America and in Europe indicate that 10-15 procedures annually can be sufficient to safely perform open AAA repair. Centres regularly performing less should consider referral. Continuous monitoring and audit of risk-adjusted peri-operative mortality rates should be practiced in all centres.”</p>
Wilt (2008)	<p>Multiple databases, 1980-November 2008:</p> <ul style="list-style-type: none"> <li>• Quality rating scale (0-5) applied to articles;</li> <li>• Included: English-language controlled studies evaluating the association between provider volumes and patient outcomes for <b>radical prostatectomy</b>;</li> <li>• Outcomes: mortality, postoperative complications, failure of cancer control,</li> <li>• Results pooled using random effects models.</li> </ul>	<p><b>17 observational studies (235,763 patients) included:</b></p> <ul style="list-style-type: none"> <li>• Hospitals with volumes &gt; mean (43 procedures/yr) had lower surgical mortality (rate difference, 0.62; CI 0.47-0.81) and morbidity (rate difference, -.97; CI, -25.- 3.6);</li> <li>• Teaching hospitals had 18% (CI, -26, -9) lower rate of complications.</li> <li>• Surgeon volume was not significantly associated with surgical mortality or positive surgical margins.</li> <li>• Rate of late urinary complications or long-term incontinence was 1.2% lower for each 10 additional; procedures performed by a surgeon annually;</li> <li>• LOS was lower, corresponding to surgeon volume.</li> </ul> <p><b>Conclusions:</b> “Higher provider volumes are associated with better outcomes after radical prostatectomy. Greater understanding of factors leading to this volume-outcome relationship, and the potential benefits and harms of increased regionalization is needed.”</p>
Henebiens (2007)	<p>Hospital volume and peri-operative mortality for <b>elective AAA repair</b>:</p> <ul style="list-style-type: none"> <li>• Multiple data bases, 1966-2006;</li> <li>• All articles comparing 30-day or in-hospital mortality rates of patients undergoing elective AAA surgery at hospitals with different volumes;</li> <li>• No language restrictions;</li> <li>• Excluded: single institution studies; duplicate reports on the same patients; and patients with ruptured AAA.</li> </ul>	<p><b>24 studies (821,810 patients) included:</b></p> <ul style="list-style-type: none"> <li>• Sample size/study: 279-484,108;</li> <li>• AAA surgery 1980-2003;</li> <li>• USA, 19 studies; Canada, 3; Europe, 2;</li> <li>• Data from health insurance databases, government registries, university hospitals, or vascular registries;</li> <li>• 18 studies reported in-hospital mortality, 6, 30-day; 4, both in-hospital and 30-day;</li> <li>• Methodologic quality of studies was variable;</li> <li>• Overall perioperative mortality, 2.30-9.9%;</li> <li>• Cut-off values for low mortality, 8-50 operations/yr.</li> <li>• Mortality in low volume hospitals, 3.0-13.8% (median 6.2); high volume, 1.80-7.4% (4.3);</li> <li>• 10 articles did not show differences between high- and low-volume hospitals.</li> </ul> <p><b>Conclusions:</b> “We found some evidence for a relation between volume of AAA surgery and peri-operative mortality. There seems to be a significant trend in favor of high volume hospitals. However we could not derive an unequivocal volume threshold for safely performing AAA surgery.”</p>

Reference	Objectives/methods	Results
Holt (2007a)	<p>Annual hospital volume and outcome after <b>CEA</b>:</p> <ul style="list-style-type: none"> <li>Multiple databases, dates not reported but reference list suggests 1986 to 2007;</li> <li>Included: articles reporting post-operative mortality and/or stroke rates;</li> <li>Meta-analysis of included studies;</li> <li>Excluded: articles investigating relation between surgeon volume and outcomes</li> </ul>	<p><b>25 articles (936,436 CEA procedures):</b></p> <ul style="list-style-type: none"> <li>Procedure dates not reported;</li> <li>Mean death rate, 1.6% (range, 0.3-5.2); mean disabling stroke, 2.7% (0.23-6.1);</li> </ul> <p><b>Results from 885,034 CEA were suitable for meta-analysis:</b></p> <ul style="list-style-type: none"> <li>Stroke rate, 0.84 (CI, 0.79-0.88) threshold value, 72 CEA/year;</li> <li>Death rate, 0.76 (0.74-0.81); 81 CEA/yr.</li> <li>Combined stroke/death, 0.73(0.68-0.78); 84 CEA/yr.</li> <li>Overall, stroke and death attributable to CEA occurred less frequently in higher volume hospitals;</li> <li>The critical volume threshold between high- and low-volume hospitals was 79 CEA/year.</li> </ul> <p><b>Conclusions:</b> <i>“Significantly lower mortality and stroke rates were achieved at hospitals providing a higher annual volume of CEA. Hospitals wishing to provide CEA should adhere to minimum volume criteria”</i></p>
Holt (2007b)	<p><b>Meta-analysis:</b> volume-outcome relation for <b>AAA surgery</b> and critical volume thresholds:</p> <ul style="list-style-type: none"> <li>Multiple databases,</li> <li>“all articles on AAA and hospital volume for AAA surgery”;</li> <li>Excluded: surgeon volume analyses; thoracic or thoraco-abdominal repairs;</li> <li>Validity assessment: presence or absence of case-mix adjustment; impact of case mix adjustment if presented; separate reporting for ruptures;</li> </ul> <p><b>HES for 2000:</b></p> <ul style="list-style-type: none"> <li>Representative of contemporary UK practice for patients undergoing AAA repair;</li> <li>Elective and urgent analyzed separately for inpatient mortality;</li> <li>Two hospital volume categories using threshold value from meta-analysis</li> </ul>	<p><b>12 articles plus HES data (421, 299 elective repair patients):</b></p> <ul style="list-style-type: none"> <li>Mean mortality rate, 9.5%;</li> <li>Mortality fell as volume increased.</li> <li>Weighted OR, 0.66 (CI, 0.65-0.67) for high volume (&gt;43 /year) Vs low-volume hospitals;</li> </ul> <p><b>Ruptured aneurysms (19 articles with 45,796 cases):</b></p> <ul style="list-style-type: none"> <li>Mortality across all studies, 37.1%;</li> <li>Weighted OR, 0.78 (CI, 0.73-0.82) at threshold of 15 procedures/yr.</li> </ul> <p><b>Conclusions:</b> <i>“Higher annual operation volumes are associated with significantly lower mortality in both elective and ruptured AAA repair. This suggests that AAA surgery should be performed only at high-volume centers.”</i></p>
Sundaresan (2007)	<b>Hospital volume-outcome association for thoracic surgical oncology:</b>	<p><b>32 volume-outcome studies, 6 organizational/consensus reports:</b></p> <ul style="list-style-type: none"> <li>Quality of evidence modest overall;</li> </ul>

Reference	Objectives/methods	Results
	<ul style="list-style-type: none"> <li>Multiple databases, 1990-2004;</li> <li>Ontario (Canada) heads of surgical oncology;</li> <li>Studies reporting association of organizational resources with improved outcome in patients with lung or esophageal cancer requiring surgical oncology services;</li> <li>Outcomes: tumor response, local control, survival, adverse events, QoL;</li> <li>guidelines and systematic reviews also eligible;</li> <li>Excluded: tumors in other locations; pre-1990 publication; non-English language.</li> </ul>	<ul style="list-style-type: none"> <li>No RCTs and other reports mostly retrospective;</li> <li>Reported outcomes confounded by: lack of risk adjustment; differences in referral patterns, procedure complexities, patterns of care, and number of volume categories;</li> <li>Studies commonly reported 30-day mortality but other outcomes generally lacking;</li> <li>Trend to improved outcomes with higher volumes;</li> </ul> <p><b>Conclusions:</b> <i>‘Overall, the quality, quantity, and generalizability of the body of evidence on the optimum organization for the delivery of cancer-related thoracic surgery identified in the literature are limited. Studies of volume and outcome relationships as indicators of patient outcome contain an inherent risk of bias and potentially confounding interactions.. There was also uneven reporting of outcomes across trials, with little consensus in the data as to what constitutes high or low volume. Notwithstanding these limitations, the results of the studies were consistent. Whether statistically significant or not, outcomes for patients were typically more favorable if they were treated by surgeons with higher volumes, surgeons with more experience, or by specialists in thoracic surgery. In terms of hospital criteria that might influence patient outcomes, treatment in higher volume hospitals and in specialist and teaching hospitals rather than general hospitals was generally associated better patient outcomes. In none of these studies was there evidence of specific structural or process factors that might have been responsible for the volume-outcome relationship.’</i></p>
Young (2007)	<p>Relationship of surgeons’ annual caseload of <b>elective open AAA repair</b> to mortality:</p> <ul style="list-style-type: none"> <li>Multiple databases plus reference lists;</li> <li>Excluded: hospital volume or ruptured AAA thoracic or thoraco-abdominal aneurysms;</li> <li>Quality appraisal for: degree and method of case-mix adjustment; separate reporting for ruptured Vs elective repair;</li> </ul>	<p><b>2466 citations retrieved, 6 (51,453 cases) eventually included in meta-analysis:</b></p> <ul style="list-style-type: none"> <li>OR for mortality rates of high- Vs low-volume surgeons: 0.56 (CI, 0.54-0.57; P&lt;.00001) at weighted mean threshold o between high and low volume of 13 AAAs/year;</li> <li>All 6 studies reported statistically significant reduction in mortality with increased operating volumes.</li> <li>No significant statistical heterogeneity demonstrated for meta-analysis.</li> <li>Sensitivity analysis by excluding largest trial: OR, 0.57 (CI, 0.53-0.62);</li> <li>Random effects analysis of complete data set: for dichotomous outcomes: OR. 0.58.</li> </ul> <p><b>Conclusions:</b> <i>“As surgeons performed higher annual volumes of elective open AAA repairs, significantly lower mortality rates were demonstrated. Surgeons wishing to perform elective AAA repairs should achieve a minimum case volume of 13 repairs per annum.”</i></p>
Hoornweg (2007)	<b>Meta-analysis:</b> recent literature on mortality after <b>RAAA</b> treated	<b>146 studies (60,822 patients) met inclusion criteria:</b>

Reference	Objectives/methods	Results
	<p>with open surgery, changes over time, concordance of hospital registries with national registries, and effects of patient age, hospital volume and type of surgeon:</p> <ul style="list-style-type: none"> <li>• Multiple databases, 1991-2000;</li> <li>• English, French, Spanish, Dutch;</li> <li>• Any prospective or retrospective study evaluating conventional surgery in patients with RAAA and describing an original patient series;</li> <li>• RAAA defined as presence of blood outside aortic wall on ultrasound, CT, or confirmed during surgery;</li> <li>• Investigators clearly distinguished RAAA from symptomatic AAA.</li> <li>• Excluded: studies reporting solely on subgroups (e.g., octagenarians).</li> </ul>	<ul style="list-style-type: none"> <li>• 33 years, mid-time point of studies 1970-2003;</li> <li>• 115 studies reported in-hospital or 30-day mortality, 1 study reported intra-operative mortality only, 37 reported intra-operative mortality, 24 reported number of patients dying before surgery.</li> <li>• 58 articles reported mean age, 67 distinguished gender, 69 allowed calculation of number of operated patients/yr/hospital.</li> <li>• 4 articles reported type of surgeon, 20 data from a national registry;</li> <li>• 17 prospective studies, 52 retrospective, 47 did not specify.</li> </ul> <p><b>Meta-analysis:</b></p> <ul style="list-style-type: none"> <li>• Weighted mean overall mortality, 48.5% (CI, 48.1-48.9);</li> <li>• Weighted mean intra-operative mortality from 37 studies, 13.3% (CI, 12.3-14.3).</li> </ul> <p><b>Meta-regression:</b></p> <ul style="list-style-type: none"> <li>• Overall mortality reduced 1.6% over 33 years (NS; <math>p = 0.84</math>);</li> <li>• Intra-operative mortality increased 1.2% over 29 years (NS; <math>p = 0.69</math>);</li> <li>• 58 articles reporting age: significant change over time (<math>P = 0.03</math>);</li> <li>• 58 studies reporting hospital volume per year: positive association with overall mortality (<math>p = 0.04</math>);</li> <li>• Mortality rates decrease as hospital volume increases but CIs are wide and very few centers perform &gt; 30 procedures/yr;</li> <li>• No significant differences in hospital records Vs national registry: mean difference, 2.1% (CI, -6.9-2.8%; <math>p = 0.4</math>);</li> <li>• Only 4 studies reported surgeon subspecialty, so analysis was not meaningful.</li> <li>• Pooled overall difference for prospective studies (46.7%; CI, 36.7-56.7) Vs. retrospective (41.1%; 32.5-49.7); but small subgroup of prospective studies makes interpretation difficult.</li> </ul> <p><b>Publication bias:</b> Funnel plots were symmetrical, so no obvious bias.</p> <p><b>Conclusions:</b> <i>"This meta-analysis suggests that mortality of patients with RAAA treated by open surgery has not changed over the past 15 years. This could be explained by increased age of patients undergoing RAAA repair."</i></p>
van Heek (2005)	<p><b>Systematic review:</b></p> <ul style="list-style-type: none"> <li>• Multiple databases, 1966-2004 plus manual cross reference search of reference lists;</li> <li>• English language papers;</li> </ul>	<p><b>Review: 12 observational studies (19,688 patients):</b></p> <ul style="list-style-type: none"> <li>• RR of dying in a high volume hospital Vs. low volume: 0.07-0.76; inversely related to arbitrarily defined cutoff values.</li> </ul>

Reference	Objectives/methods	Results
	<ul style="list-style-type: none"> <li>mortality after pancreatic resection and hospital volume;</li> <li>all studies comparing mortality rates for patients undergoing pancreatic resection between hospitals with different volumes considered;</li> <li>Pancreatic resections: pylorus-sparing pancreaticoduodenectomy or total pancreatectomy for benign or malignant periampullary tumors;</li> <li>Cutoff value defining high and low volume reported</li> <li>Dependent variable/outcome measure: hospital or 30-day mortality</li> <li>Excluded: single-institution studies; studies not reporting data for calculation of mortality rates; studies including only acute pancreatitis.</li> <li>Reviews authors calculated RR for death from individual studies but did not pool results due to heterogeneity among studies</li> </ul> <p><b>Intervention:</b></p> <ul style="list-style-type: none"> <li>Volume-mortality results from national pancreatic resection registry published and presented at surgical meetings as: "ongoing plea for centralization in the Netherlands".</li> </ul>	<p><b>Intervention: 5 evaluations of registry data within a decade</b></p> <ul style="list-style-type: none"> <li>Mortality at hospitals performing &lt; 5 pancreatic resections/yr, 13.8%-16.5% Vs. 0-3.5% in hospitals with &gt; 24 /yr.</li> <li>Despite repetitive plea for centralization, information dissemination without government regulation resulted in no change to referral patterns.</li> <li>2001-2003: 454/792 patients (57.3%) had resections in low volume hospitals Vs 280/428 (65.4%) in 1994-1996.</li> </ul> <p><b>Conclusions:</b> <i>"The data on hospital volume and mortality after PR are too heterogeneous to perform a meta-analysis, but a systematic review shows convincing evidence of an inverse relationship between hospital volume and mortality and enforces the plea for centralization. The 10-year lasting plea for centralization among the surgical community did not result in a reduction of the mortality rate after PR of change the referral pattern in the Netherlands."</i></p>
Killeen (2005)	<p><b>Outcomes of oncological procedures according to provider volume:</b></p> <ul style="list-style-type: none"> <li>Multiple databases, 1984-2004;</li> <li>English-language, population- or community-based cohort;</li> <li>Volume as independent variable; health outcome as dependent variable;</li> <li>Excluded: medical therapies; samples not community or population based; volume not independent variable</li> <li>Included studies analyzed by organ system and evaluated for generalizeability.</li> </ul>	<p><b>41 studies included (13 based on clinical data):</b></p> <ul style="list-style-type: none"> <li>11 studies for pancreatic resection: quality scores, 5-10 (median 7);</li> <li>10 studies for esophageal resection quality 6-10 (median 7);</li> <li>All studies showed inverse relationship of variable magnitude between volume and outcome, or no volume-effect.</li> </ul> <p><b>Conclusions:</b> <i>"High-volume providers have a significantly better outcome for complex cancer surgery, specifically for pancreatectomy, esophagectomy, gastrectomy, and rectal resection."</i></p>
<b>C: Systematic reviews for other topics relevant to rural health care</b>		
Vernooij (2007)	<p><b>Effects of specialized care for ovarian cancer patients:</b></p> <ul style="list-style-type: none"> <li>Studies of relationship between care setting (volume or teaching status of hospital; general or specialist gynecologist) and outcome in patients with epithelial ovarian cancer;</li> <li>Multiple databases, Jan 1991- Nov 2006;</li> <li>Original cohort or population studies reporting: survival,</li> </ul>	<p><b>19 studies met inclusion criteria:</b></p> <ul style="list-style-type: none"> <li>No available RCTs;</li> <li>Gynecologic oncologists: more frequently performed adequate staging and optimal de-bulking: 1.4 times more often than general gynecologists (CI, 1.2-1.5); to no macroscopic disease (RR, 2.3; CI, 1.5-3.5); an in specialized hospitals (RR, 1.9-6.0);</li> <li>No differences in postoperative complication rates;</li> </ul>



Reference	Objectives/methods	Results
	<p>staging, optimal de-bulking (reduction to &lt; 2 cm), complications, postoperative mortality and chemotherapy by general gynecologists, gynecologic oncologists, and general surgeons separately; and adjusting survival by at least age and stage of disease;</p> <ul style="list-style-type: none"> <li>Excluded studies with patients diagnosed before 1990; case reports or series;</li> </ul>	<ul style="list-style-type: none"> <li>pooled RR of receiving chemotherapy 1.14 (CI, 1.5-2.5), but differences in chemotherapy did not lead to differences in survival;</li> <li>Long-term survival better in specialized hospitals;</li> <li>Survival by gynecologic oncologist better in subgroups: 5- to 8-month median for advanced disease.</li> </ul> <p><b>Conclusions:</b> <i>"The outcome of ovarian cancer is better when treatment is provided by a gynecologic oncologist or in a specialized hospital."</i></p>
Glazebrook (2006)	<p>Quasi-systematic review:</p> <ul style="list-style-type: none"> <li>Medline plus internet;</li> <li>Articles addressing <b>rural and remote medical education</b>; focus on procedural skills;</li> <li>Publication dates, research question, study types, quality appraisal, language not reported;</li> </ul>	<p><b>600 potentially relevant articles initially identified, 66 included:</b></p> <ul style="list-style-type: none"> <li>World-wide workforce shortages in rural procedural medicine;</li> <li>Rural communities are disadvantaged re access to health services;</li> <li>Rural doctors are expected to maintain knowledge, technical procedural skills, and to provide acute care in a variety of clinical areas: emergency medicine; obstetrics; anesthesia. Rural doctors provide primary care, procedural, and public health services.</li> <li>Australia: rural doctors provide more procedural services with increasing rurality or remoteness.</li> <li>Canada: rural doctors more likely to practice in emergency departments, hospital settings, or nursing homes, and to provide obstetric services, even though other primary care doctors have reduced participation in such activities.</li> </ul> <p><b>Conclusions:</b> <i>"Retention of rural doctors and the difficulties faced by them in maintaining advanced procedural skills can be addressed, at least in part, by increased support for flexible continuing medical education and professional development such as specific skills rural training programs, the availability of group practice opportunities, improved hospital facilities, reasonable workloads, financial incentives, locum assistance, improved housing quality, and better educational support for families. We noted a positive association between dedicated rural training programs and the recruitment of rural doctors. Factors associated with these successful training programs include: rural fellowships, explicit rural mission, rural location, rural program directors, and procedural orientation."</i></p>
Parsons (2003)	<p><b>Systematic review:</b> barriers to implementing research findings in rural and remote settings and how barriers have been addressed.</p> <ul style="list-style-type: none"> <li>Multiple databases;</li> <li>1990-2002;</li> <li>English-language articles;</li> </ul>	<p><b>183 papers, 3 included:</b></p> <ul style="list-style-type: none"> <li>Majority excluded because they did not relate specifically to rural/remote context;</li> <li>No experimental data on implementation of research in these settings;</li> <li>Descriptive research (surveys) indicated: problems experienced by general practitioners are exacerbated by rural and remote settings: isolation, lack of time</li> </ul>

Reference	Objectives/methods	Results
	<ul style="list-style-type: none"> <li>Articles providing information on: barriers to implementation of evidence in rural or remote areas; interventions for implementation of evidence;</li> <li>Outcomes: barriers; patient health status and/or satisfaction with care; uptake of interventions (e.g. change in practice) by target professionals; sustainability, cost, or cost-effectiveness of interventions.</li> </ul>	<p>and locum cover, poor IT infrastructure.</p> <p><b>Conclusions:</b> <i>“There is a paucity of empirical literature on implementing evidence-based practice in rural and remote settings. This is in contrast to the large amount of literature available on implementing evidence in other clinical settings. A clear finding from the literature is that getting evidence into practice needs to be context-specific and yet very little research has been conducted in the rural and remoter context. Research is needed into how evidence can be implemented in contextually specific ways in rural and remote areas.”</i></p>
Gruen (2003): Cochrane review	<p>Overview of specialist outreach clinics in primary care and rural hospital settings:</p> <ul style="list-style-type: none"> <li>Multiple databases including Cochrane specialized registers, 1966-2002;</li> <li>RCTs, controlled before-and-after, interrupted time series;</li> <li>Visiting specialist outreach clinics providing simple consultations or as part of complex multifaceted interventions;</li> <li>Outcomes: objective measures of access, quality, health outcomes, satisfaction, service use, or cost.</li> </ul>	<p><b>73 outreach interventions:</b></p> <ul style="list-style-type: none"> <li>Covering many specialties, countries, and settings;</li> <li>9 studies included;</li> <li>Most comparative studies came from non-disadvantaged populations in developed countries.</li> <li>Simple “shifted outpatients” (outreach provides similar consultations, investigations and procedures to those of hospital clinics) styles of specialist outreach improved access, but there was no evidence of impact on health outcomes.</li> <li>Specialist outreach as part of complex interventions (involving collaboration with primary care, education, or other services) was associated with improved health outcomes, more efficient and guideline-consistent care, and less use of inpatient services.</li> <li>The additional cost of outreach may be balanced by improved health outcomes.</li> </ul> <p><b>Conclusions:</b> <i>“This review supports the hypothesis that specialist outreach can improve access, outcomes, and service use, especially when delivered as part of a multifaceted intervention. The benefits of simple outreach models in urban non-disadvantaged settings seem small. There is a need for good comparative studies of outreach in rural and disadvantaged settings where outreach may confer most benefit to access and health outcomes.”</i></p>
Campbell (1999)	<p><b>Cancer treatment programs in rural and remote areas:</b></p> <ul style="list-style-type: none"> <li>Multiple databases, 1978-1997;</li> <li>Eligible studies: described or cited a description of cancer treatment program in rural areas; evaluated the program, or identified problems; and were conducted in an industrialized country.</li> </ul>	<p><b>51 papers described rural cancer treatment programs:</b></p> <ul style="list-style-type: none"> <li>15 eligible for review: oncology outreach; tele-oncology; and rural hospital initiatives;</li> <li>All studies were small and only 2 were controlled: suggestive rather than conclusive evidence;</li> <li>Shared outreach care was safe and seemed to make specialist care more accessible to outlying patients;</li> </ul>

Reference	Objectives/methods	Results
		<ul style="list-style-type: none"><li>• Tele-oncology (consultations via tele-video) may be an acceptable adjunct.</li></ul> <p><b>Conclusions:</b> <i>“Larger and more methodologically robust studies are justified and should be conducted.”</i></p>

Table 2: Effects of service regionalization

Reference	Objectives/other details	Results/Comments
<b>A: Modeled or estimated</b>		
Brookfield (2009)	<b>Effect of hospital volume and teaching status on outcome for gynecologic malignancies:</b> <ul style="list-style-type: none"> <li>• endometrial, cervical, ovarian, vulvar carcinomas; uterine sarcoma;</li> <li>• Florida cancer registry, incident cases, 1990-2000;</li> <li>• Teaching status according to AAMC</li> </ul>	<p><b>48,981 patients:</b> endometrial (43.2%); Ovarian (30.9%); cervical (20.8%); vulvar (4.6%); uterine sarcoma (0.5%):</p> <ul style="list-style-type: none"> <li>• <b>Univariate analyses:</b> Patients at HVHs were significantly younger and had better 30- and 90-day survival for cervical, ovarian, and endometrial;</li> <li>• <b>Multivariate analyses:</b> no significant benefit for patients at teaching or HVHs;</li> <li>• <b>Prognostic significance at presentation:</b> age &gt; 65; African-American race advanced disease;</li> <li>• Surgery and chemotherapy both significantly associated with improved survival.</li> </ul> <p><b>Conclusions:</b> <i>"No difference inpatient survival was observed for any gynecologic malignancy based upon treating hospital characteristics. Although instances of improved outcomes may occur, overall further regionalization would not appear to significantly improve patient survival."</i></p>
Holt (2008)	<b>Model for reconfiguration of specialized vascular services in England:</b> <ul style="list-style-type: none"> <li>• Comparison of current service configurations with a theoretical model (centralized hub-and-spoke);</li> <li>• Algorithm for elective AAA repair and CEA;</li> <li>• National dataset: 2000-2005; patient demographics statistical demonstration of safety; hospital annual volume; travel distance and time; in-hospital mortality and complications.</li> <li>• Organizations delivering vascular services in England, not all of which corresponded to physical hospitals.</li> </ul>	<p><b>48 hubs required to provide adequate coverage:</b></p> <ul style="list-style-type: none"> <li>• Majority of patients traveling &lt; 1 hr to access inpatient vascular surgery: median spoke to hub travel time, 28.5 min (range, 4-108); median distance, 16 miles (0.5-80);</li> <li>• Reductions in number of deaths: for AAA (P&lt;0.001); and CEA (P=0.016).</li> </ul> <p><b>Conclusions:</b>  <i>"Adoption of this strategic model may lead to improved outcome after AAA and CEA. It can be used as a model for the regionalization of specialized surgery. The model does not take into account the complexity of providing a comprehensive vascular service in every locality."</i></p>
Miyata (2008)	<b>Cardiovascular surgery in Japan:</b> <ul style="list-style-type: none"> <li>• National survey, 525 hospitals conducting cardiovascular surgery (CABG, valve, thoracic aorta, congenital), 2001-2004;</li> <li>• Categories of hospital volume: &lt; 10; 10-24; 25-49; 50-74/yr;</li> <li>• Effects of regionalization on 30-day mortality and additional travel distance;</li> </ul>	<p><b>209,221 procedures:</b></p> <ul style="list-style-type: none"> <li>• 30-day mortality without regionalization, 4.62%;</li> <li>• After regionalization, 4.40% for volumes &lt; 10; 4.28% for 10-24; 3.78% for 25-49; 3.12% for 50-74;</li> <li>• Average number of patients traveling ≥ extra 30 km after regionalization: 0.8 for &lt; 10; (0.001% of total patients); 12.3 for 10-24 (0.02%); 88.3 for 25-49 (0.2%); 179.3 for 50-74 (0.3%).</li> </ul>

Reference	Objectives/other details	Results/Comments
		<p><b>Conclusions:</b> <i>“The results indicate that, after regionalization, the 30-day mortality rate did improve for hospitals with 25-49 and 50-74 annual surgeries. While increased travel times may be critical for patients requiring emergency surgery, the results suggest that low-volume hospitals get relatively few such cases. In many regions, improving the transportation system may be more effective than maintaining a low volume.”</i></p>
Glance (2007)	<p><b>To compare population health effects of strategies for service regionalization:</b></p> <ul style="list-style-type: none"> <li>• Selective referral to high-quality hospitals;</li> <li>• Selective referral to high-volume hospitals;</li> <li>• Selective avoidance of low-quality hospitals;</li> <li>• Selective avoidance of low-volume hospitals;</li> <li>• Patients undergoing AAA surgery, CABG, or coronary angioplasty in California, 1998-2000;</li> <li>• Separate random-intercept models for risk-adjusted (gender, comorbid conditions, disease stage) in-hospital death for each procedure.</li> </ul>	<p><b>243,000 patients hospitalized for one of three procedures during study period:</b></p> <ul style="list-style-type: none"> <li>• With hospital as unit of analysis, volume is not an accurate proxy for hospital quality in these study populations;</li> </ul> <p><b>Results by procedure:</b></p> <ul style="list-style-type: none"> <li>• <b>CABG:</b> decrease in mortality from 3.02-2.42% (<math>P &lt; 0.05</math>); 70% of patients would be transferred to high volume centers;</li> <li>• 91% of cardiac surgery units would close;</li> <li>• <b>AAA surgery:</b> reduction in mortality from 12.6-11.6% (<math>P &lt; 0.05</math>); transfer of 94% of patients and elimination of surgery at 99% of hospitals currently performing it;</li> <li>• <b>Coronary angioplasty:</b> implementation of Leapfrog criteria would not produce significant reduction in mortality</li> </ul> <p><b>Overall results:</b></p> <ul style="list-style-type: none"> <li>• Selective referral to high-volume centers (defined by Leapfrog cut offs) would be only moderately effective (2-20% relative reduction in mortality) and extremely disruptive (70-99% reduction in number of hospitals treating these conditions);</li> <li>• Selective referral to high-quality centers resulted in dramatic reduction in mortality (50%) but would also be highly disruptive (&gt;80% of patients would be re-directed);</li> <li>• Selective avoidance of low volume hospitals would not improve mortality;</li> <li>• Selective avoidance of low quality hospitals resulted in small improvement in mortality (2-6%) with relatively minor disruptions in referral patterns.</li> </ul> <p><b>Conclusions:</b> <i>“Efforts to use volume standards as the basis for evidence-based hospital referrals should be re-evaluated by all stake-holders before promoting further efforts to regionalize health care delivery using volume cutoffs.”</i></p>
Chappel (2006)	<p><b>Impact of regionalization on small (&lt; 50 beds) rural hospitals in New York State:</b></p> <ul style="list-style-type: none"> <li>• HCUP data set used to identify all admission to small rural hospitals and total charges/admission;</li> </ul>	<p>14/18 small rural hospitals in New York state performed one of the nine procedures during that time period:</p> <ul style="list-style-type: none"> <li>• All performed colectomy. AAA repair, CEA esophagectomy, and pancreatectomy were performed infrequently with the exception of one hospital.</li> </ul>

Reference	Objectives/other details	Results/Comments
	<ul style="list-style-type: none"> <li>Hospitalizations 1998-2001 including 1/9 procedures with documented volume-outcome association (AAA repair, AVR, CEA, colectomy, CABG, cystectomy, esophagectomy, pancreatotomy, pulmonary resection);</li> <li>Urgent or elective recorded;</li> <li>Revenue for procedures estimated and compared with total inpatient revenue for each rural hospital</li> </ul>	<ul style="list-style-type: none"> <li>None of the hospitals performed AVR, CABG, or pulmonary resection.</li> <li>Most revenue attributable to colectomy, with all other procedures combined accounting for &lt;0.2% of revenue for the 14 hospitals.</li> </ul> <p><b>Conclusions:</b> <i>"If all aortic aneurysm repairs, major cardiothoracic procedures, carotid endarterectomies, cystectomies, and pancreatectomies in New York State were regionalized to higher volume hospitals, no small rural hospitals would experience substantial impact in terms of rural hospital procedure volume and revenue. Even regionalization of colectomy would have a small impact on inpatient volume and revenue."</i></p>
Ward (2004)	<p><b>Impact of Leapfrog volume standards in Iowa:</b></p> <ul style="list-style-type: none"> <li>5 procedures (CABG, AAA repair, coronary angiography, esophageal and pancreatic cancer);</li> <li>2001 Iowa discharge database;</li> <li>Hospitals categorize as meeting/not meeting volume standards and by AHA data (bed-size, admissions, staff/bed, teaching status, ownership, membership in system, rural/urban);</li> </ul>	<ul style="list-style-type: none"> <li><b>CABG:</b> 13 hospitals performed, 1 met standard;</li> <li><b>Esophageal cancer:</b> 14 hospitals performed, 1 met standard;</li> <li><b>Pancreas:</b> 13/1;</li> <li><b>AAA repair:</b> 24/2;</li> <li><b>Coronary angioplasty:</b> 17/10;</li> <li>Relatively few IA hospitals performed these procedures;</li> <li>Hospitals meeting volume standards tend to be larger, receive more transfers, and do fewer of the procedures on urgent basis, but otherwise did not differ from not meeting standard hospitals on risk-adjusted mortality;</li> <li>The impact of volume standard implementation would be substantial in terms of travel time for some procedures (CABG, esophageal and pancreas) and lost revenue for hospitals, but not offset my mortality improvements.</li> </ul> <p><b>Conclusions:</b> <i>"Evidence-based referral would be associated with substantial burden for some patients and hospitals in Iowa. This negative impact does not appear to be offset by improvement in in-hospital mortality rates."</i></p>
Dimick (2004b)	<p><b>Regional availability of high-volume hospitals:</b></p> <ul style="list-style-type: none"> <li>CABG, elective AAA repair, pancreas resection;</li> <li>National Medicare population, 1999-2001;</li> <li>Leapfrog 2003 volume standards for these procedures applied to Medicare data extrapolated to NIS (total number of cases for all payers; hospitals with average total volume &gt; Leapfrog standard considered HVH);</li> <li>Patients' access to HVH in each of 306 US hospital referral regions;</li> </ul>	<ul style="list-style-type: none"> <li>Overall, more than half of surgical cases performed in low-volume hospitals during study period.</li> <li>Availability of HVHs varied widely across geographic regions for each procedure.</li> <li>More HRRs had at least one HVH for CABG (42%) and AAA repair (44%) than for pancreas (16%).</li> <li>Although many HRRs along the Pacific Coast and parts of Intermountain West lacked HVHs for all procedures, regional availability of HVHs varied widely by procedure.</li> </ul>

Reference	Objectives/other details	Results/Comments
		<b>Conclusions:</b> <i>“Efforts to improve surgical quality will need to look beyond volume-based referral alone. As outlined in this paper, such strategies are impractical in many parts of the United States lacking high-volume centers. Moreover, although volume is clearly linked to lower mortality rates with many procedures on average, it remains a poor predictor of individual hospital performance...getting all patients to high-volume centers would go only so far in improving surgical outcomes.”</i>
Peterson (2004)	See Table 1	
Finlayson (2003)	<b>Markov decision analysis:</b> life expectancy and regionalization effects: <ul style="list-style-type: none"> <li>• Patients undergoing resection for pancreatic, lung, or colon cancer;</li> <li>• National Medicare database, 1994-'99;</li> <li>• Risks of late mortality from published studies.</li> <li>• Policy analysis: potential life years gained by moving cancer patients to HVHs (minimum volume standards to prohibit procedures at VLVHs; or restrict procedures to VHVHs)</li> </ul>	<b>400,000 patients during study period:</b> <ul style="list-style-type: none"> <li>• Life expectancy increased steadily with volume for all cancers;</li> <li>• linearly for pancreas (1.9 yrs at VLVHs, 3.6 at VHVHs);</li> <li>• Lung cancer: 5.4 Vs 6.5 yrs;</li> <li>• Colon cancer; 7.4 Vs 6.8 yrs;</li> <li>• Differences in life expectancy across volume strata largely attributable to differences in long-term rather than in-hospital survival.</li> <li>• Policy: regionalizing surgery for colon cancer would produce greatest overall life expectancy gains, but would also require moving most patients.</li> </ul> <b>Conclusions:</b> <i>“Patients aged 65 and older with pancreatic, lung, and colon cancer have substantially greater life expectancy after cancer resection at higher volume hospitals. Further work is needed to understand the mechanisms underlying the differences in performance across hospitals in cancer care.”</i>
Birkmeyer (2001)	<b>Potential benefits of full nationwide implementation of Leapfrog volume standards:</b> <ul style="list-style-type: none"> <li>• 5 procedures: CABG; AAA repair; coronary angioplasty; esophagectomy; CEA;</li> <li>• NIS for 1997 used to estimate total number of each procedure/ yr in US metropolitan areas (Leapfrog exempts rural hospitals); with assumption of 80% of procedures performed in urban hospitals;</li> <li>• Projected effectiveness of volume standards (RR for mortality for each procedure using results from Dudley (2000; Table 1, Section A);</li> <li>• Estimates of lives saved based on assumptions of numbers of patients effected and strength of evidence for volume</li> </ul>	<b>Full nationwide implementation of Leapfrog volume standards for these procedures would save 2581 lives (rank order) :</b> <ul style="list-style-type: none"> <li>• CABG (1486 lives);</li> <li>• AAA repair (464);</li> <li>• Coronary angioplasty (345);</li> <li>• Esophagectomy (168);</li> <li>• CEA (118).</li> </ul>

Reference	Objectives/other details	Results/Comments
	standards; <ul style="list-style-type: none"> <li>Excluded: most patients undergoing emergent operations who would not be appropriate for transfer;</li> <li></li> </ul>	
Rouse (2001)	<p><b>“If, for common elective procedures, the NHS instituted a high-volume purchasing policy that requires consultant firms to perform a minimum of 50 procedures a year, what proportion of firms would have to stop providing these procedures?”</b></p> <ul style="list-style-type: none"> <li>Database of patients treated in West Midlands (UK) NHS facilities, 1994-1997;</li> <li>50 procedure threshold based on 1995 UK policy for cancer care</li> <li>Demographics and health service provision typical of rest of UK;</li> <li>“basket” of common elective procedures: cataract removal; gall bladder excision; fiber-optic procedures of upper gastrointestinal tract; ligation or stripping of varicose veins; primary or recurrent inguinal hernia repair; prosthetic knee replacement; total hip replacement; transurethral resection of prostate; vaginal hysterectomy;</li> <li>Excluded: consultant firms with &lt;1 year of data (4% of procedures); 1% of procedures with incomplete data</li> </ul>	<p><b>Wide range of volumes within procedure categories:</b></p> <ul style="list-style-type: none"> <li>All cataract providers did &gt; 50.yr;</li> <li>No provider did &gt; 50 recurrent inguinal hernia repairs;</li> <li>5 procedure threshold for entire “basket”: 40% of firms would no longer be eligible; lower threshold of 1 /month: 20% no longer eligible.</li> </ul> <p><b>Conclusions:</b> <i>Introduction of a high-volume policy would affect a considerable number of firms, as many NHS consultant firms perform some common elective procedures infrequently. Some consultants would see the introduction of a high-volume policy as an opportunity to further specialize and super-specialize. Others would see it as a policy that restricts them to providing a narrower range of procedures, makes their professional practice less interesting, and reduces their professional autonomy. Postgraduate training institutions need to consider the possibility and implications of high-volume policies, as many junior doctors would probably need to learn to provide a narrower range of skills than at present.”</i></p>
Rohrer (1997)	<p><b>Estimate of impact of enforcing safe cardiovascular procedure volume in Iowa:</b></p> <ul style="list-style-type: none"> <li>Volume data for CABG, vascular surgery, cardiac valve surgery, and catheterization in 1990;</li> <li>Population projection from most recent census (1980);</li> <li>Assumptions: current per capita procedure rates; reduced repeat procedure rates;</li> <li>Volume thresholds calculated from sensitivity analyses of average state utilization rates in 1990 and shifting patients away from low-volume centers.</li> </ul>	<p><b>In 1990:</b></p> <ul style="list-style-type: none"> <li>12 hospitals in Iowa performed CABG, with volume range 15-346, including several low volume centers serving communities with below average CABG rates;</li> <li>33 hospitals performed vascular procedures, range 3-825 cases;</li> <li>Cardiac catheterizations in 22 hospitals, mean volume 231 cases (6-869);</li> </ul> <p><b>With volume thresholds:</b></p> <ul style="list-style-type: none"> <li>12 hospitals doing CABG would be reduced to 2;</li> <li>10 doing valve surgery to one;</li> <li>22 doing catheterization to two.</li> </ul> <p><b>Conclusions:</b> <i>...”the impact of a regionalization policy clearly would be substantial. State certificate-of-need agencies would have to be revitalized. These agencies would need to be strong enough to withstand intense political pressure. After all,</i></p>



Reference	Objectives/other details	Results/Comments
		<i>many of the physicians currently performing certain procedures at small hospitals would have to refer their patients elsewhere if volume threshold criteria were adopted. Furthermore, the hospitals losing their referral bases would experience declines in revenue, and local economies would have to be restructured. Nevertheless, regionalization is the logical solution to the problem of low volumes, since a true regionalization policy ensures that primary care access points remain in place, even if secondary and tertiary care are more centralized."</i>
<b>B: Actual regionalization effects</b>		
McColl (2008)	<b>Hepatic resection in Canada:</b> <ul style="list-style-type: none"> <li>All provinces except Quebec;</li> <li>National discharge data, 1995-2004.</li> <li>HVH <math>\geq 10</math> procedures/yr; LVH, 1-9/yr;</li> <li>Outcomes: in-hospital mortality; LOS;</li> <li>Adjustments: patient demographics, CCI, admission status, indication for operation, province; against reference year 2001;</li> <li>Comparison: US liver resection data from Dimick (2004; Table 3);</li> <li>Sensitivity analyses across broad range of volume category definitions;</li> </ul>	<b>9,912 procedures during study period:</b> <ul style="list-style-type: none"> <li>Mean age, 59 yrs;</li> <li>Proportion at HVH: 42% in 1995; 84% in 2004;</li> <li>Overall mortality for entire study period: 5.0%; LVHs, 6.1%; HVHs, 4.6%; (difference NS, <math>p = 0.7451</math>);</li> <li>Mean LOS: HVH, 12.1 days (1-267; LVH, 13.2 (1-188)</li> <li>Multivariate analysis: factors predictive of mortality were age, gender, year of operation, operative indication, CCI, admission status;</li> <li>Canada Vs. US: proportion of resections for secondary malignancies similar; hospital volume not significant predictor for mortality in Canada Vs significant in US.</li> </ul> <p><b>Conclusions:</b> "We have shown that outcomes following hepatic resectional surgery are improving and that hospital volume may not be related to outcome as it is in the US."</p>
Scarborough (2008)	<b>Hepatic resection:</b> temporal trends in provider volume and differential access to high-volume providers: <ul style="list-style-type: none"> <li>NIS, 1988-2003</li> </ul>	<b>Temporal trends:</b> <ul style="list-style-type: none"> <li>increasing percentage of patients 18-59yrs; decreasing percentage 60-69;</li> <li>increasing percentage with substantial underlying comorbidities;</li> <li>Apparent shift away from urban non-teaching to urban teaching;</li> <li>Increasing percentage of patients in HVHs (<math>&gt; 45</math> procedures/yr: 2.7% to 29.9%; <math>P &lt; 0.0001</math>) and decreasing use of LVHs (<math>&lt; 7</math>/yr: 61.6% to 30.7%);</li> <li>Post-operative mortality: 10.0% to 4.7% (<math>P &lt; 0.001</math> after adjusting for demographics and comorbidities);</li> <li>Early: mortality in lowest and highest volume hospitals NS different from overall mortality; Later: lowest volume mortality significantly higher than mean and highest volume significantly lower.</li> </ul> <p><b>Patient demographics over time:</b></p>

Reference	Objectives/other details	Results/Comments
		<ul style="list-style-type: none"> <li>Early: specific populations evenly spread among hospitals Vs. later: greater discrepancies in distribution among categories of hospitals with LVHs treating larger proportions of older patients, higher CI, and African Americans.</li> </ul> <p><b>Conclusions:</b> <i>“Regionalization of liver resection is occurring at both the level of the individual surgeon and the hospitals where these procedures are performed. These trends in provider volume might be associated with increasing discrepancies in outcomes and in patient demographics among different volume categories of hospitals.”</i></p>
Yermilov (2008)	<p><b>To examine readmission data following PD in context of increased regionalization:</b></p> <ul style="list-style-type: none"> <li>California cancer registry, 1994-2003; linked to</li> <li>CA Office of statewide planning and development database excluding patients who died within 30 days</li> <li>Readmissions within 1 year analyzed for: timing, location, and reason;</li> </ul>	<p><b>2023 patients receiving PD for cancer</b> (deaths within 30 days excluded):</p> <ul style="list-style-type: none"> <li>Median FU, 43 months;</li> <li>82% of patients followed to death;</li> <li>51% males; median age 66 years;</li> <li>Differences readmission Vs no readmission: CCI score of zero (54.4% Vs 61.6%; <math>P &lt; 0.001</math>); low T-stage (23.6% Vs. 20.0%; <math>P &lt; 0.05</math>); stage T4 (15.8% Vs 11.1%; <math>P &lt; 0.003</math>);</li> <li>No significant difference at 1 year, adjuvant chemotherapy Vs no chemo;</li> <li>Longer surgical LOS more likely to be readmitted: 15 days Vs 13; <math>P &lt; 0.0001</math>;</li> <li>Median survival, readmission Vs no: 12.3 Vs 22.0 months; <math>P &lt; 0.0001</math>;</li> <li>1,194 patients (59% had 2,435 readmissions within 1 year (median for cohort, 2;0):</li> <li>Predictors of readmission: age &gt; 73; CCI 1 or 3; T-4;</li> <li>47% readmitted to a secondary hospital;</li> <li>Reasons for readmission: disease progression (24.3%); surgical complications (14.0%); infection (12.3%); dehydration/malnutrition/electrolyte disorders (6.2%); DVT/pulmonary embolism (3%); pain (1.5%); diabetes (1.4%);</li> <li>Assumption that regionalization was in effect during study period, but no explicit measurement or analysis.</li> </ul> <p><b>Conclusions:</b> <i>“We found a readmission rate of 59%, which is much higher than previously reported single institutional series. Concordantly, nearly half of patients were re-admitted to a secondary hospital.”</i></p>
Cooperberg (2007)	<p><b>Regionalization trends for urological malignancies:</b></p> <ul style="list-style-type: none"> <li>Bladder, renal, prostate;</li> <li>NIS, 1988-2002;</li> </ul>	<p><b>Patients and procedures:</b></p> <ul style="list-style-type: none"> <li>26,770 patients admitted to 1,764 hospitals and had radical cystectomy during study period:</li> </ul>

Reference	Objectives/other details	Results/Comments
	<ul style="list-style-type: none"> <li>Time trends in discharge rate by hospital tertile volume, geographic region, insurance status.</li> </ul>	<ul style="list-style-type: none"> <li>64,875 patients had nephrectomy at 2,182 hospitals;</li> <li>178,210 men had radical prostatectomy at 2,065 hospitals;</li> <li>Annual case volumes to define HVH: bladder (22); renal (12); prostate (26);</li> <li>Surgical and non-surgical discharges for renal and bladder from HVHs increased significantly during study period.</li> <li>increases from HVHs; bladder (67-70%); renal (67-73%); prostate cases constant during study period.</li> </ul> <p><b>Insurance status:</b></p> <ul style="list-style-type: none"> <li>Medicare/Medicaid: discharges for bladder increased significantly with time.</li> </ul> <p><b>Conclusions:</b> <i>“Nationwide Inpatient Sample data demonstrate the ongoing regionalization of urological oncology care. The policy implications of this trend are complex with potentially important benefits and risks in terms of access to and quality of care.”</i></p> <p>This study describes time trends but does not analyze regionalization effects.</p>
Laukontas (2007)	<p><b>Ruptured AAA mortality after regionalization in Finland:</b></p> <ul style="list-style-type: none"> <li>All ruptured AAA: Helsinki and Uusimaa district, 1996-2004;</li> <li>3 periods; control/baseline (1996-8); change to regionalization (1999-2002); present (2003-04);</li> <li>Hospital records: Helsinki University and death certificates of patients with rupture confirmed by laparotomy or autopsy;</li> <li>Time from admission to beginning of operation; pre-op Glasgow Aneurysm score; and risk.</li> </ul>	<p><b>626 ruptured AAA during study period:</b></p> <ul style="list-style-type: none"> <li>30-day mortality, 38%; 90-day 45%;</li> <li>4 patients treated endovascularly; 2/4 died;</li> <li>9% of patients were not operated: 23 moribund; 10, rupture not diagnosed;</li> <li>Overall population mortality, 69%;</li> <li>Operative mortality, 90 day, and population mortality unchanged during baseline and change periods; but did change for final period Vs. baseline: population-based mortality, 77%- 56% (P&lt;0.001); 90-day, 54%-28% (P= 0.002); operative, 32%-19% (P=0.001);</li> </ul> <p><b>Conclusions:</b> <i>“ Our results seem to argue in favor of centralization of emergency vascular services with adequate manpower and operative expertise in the first line and with availability of closed-unit postoperative critical care to achieve better results as these measures were associated with a positive impact on survival.”</i></p>
McPhee (2007)	<p><b>National perspective: in-hospital mortality for pancreatic resection:</b></p> <ul style="list-style-type: none"> <li>NIS, 1998-2003;</li> <li>Multivariate analyses: age; sex; hospital teaching status; hospital volume; year of procedure; payer; comorbidities;</li> </ul>	<p><b>279,445 discharges with a primary diagnosis of pancreatic neoplasm:</b></p> <ul style="list-style-type: none"> <li>39,463 (14%) of patients received pancreatic resection during that hospitalization; 6000 procedures/yr;</li> <li>Operative cohort: 52% female;</li> <li>mean age of all patients, 69; operative, 64 (range, 18-93);</li> </ul>

Reference	Objectives/other details	Results/Comments
	<ul style="list-style-type: none"> <li>Volume levels: low (&lt; 5/yr); medium (5-18/yr); high (&gt; 18/yr) tracked over time through study period.</li> </ul>	<ul style="list-style-type: none"> <li>Operations: 63% for malignancy of head, neck or periampullary region;</li> <li>All operated patients: 5.9% crude in-hospital mortality with decrease over time (7.8% in 1998 to 4.6% in 2003; <math>P &lt; 0.0001</math>);</li> <li>Higher mortality at low- Vs high-volume centers (OR, 3.3; CI, 2.3-4); and med Vs high-volume (OT, 2.1; CI, 1.5-3.0);</li> <li>Proportion of procedures at high-volume centers changed from 30% to 39% during 6 yr study.</li> </ul> <p><b>Conclusions:</b> <i>"This large observational study demonstrates an improvement in operative mortality for patients undergoing pancreatectomy for neoplastic disease from 1998 to 2003. In addition, a greater proportion of pancreatectomies were performed at high volume centers in 2003. The regionalization of pancreatic surgery may have partially contributed to the observed decrease in mortality rates."</i></p>
Langer (2007)	<p><b>Ontario Province, Canada: pancreatic cancer surgery:</b></p> <ul style="list-style-type: none"> <li>1997: provincial mortality following pancreatectomy, 10.2%;</li> <li>Cancer Care Ontario standards (2001): hospital resources, organization, infrastructure; volume of pancreas surgery <math>\geq 10</math>/yr, total HPB <math>\geq 25</math>/yr;</li> <li>public reporting (prevention, screening, treatment, outcomes) via web beginning in 2004;</li> <li>with higher rate in LVHs, lower in HVHs</li> </ul>	<p><b>By 2005:</b></p> <ul style="list-style-type: none"> <li>cases treated in hospitals meeting volume standards increased from 17.8% to 60.8%;</li> <li>Provincial hospital mortality decreased from 10.2% to 4.5%.</li> </ul> <p><b>Conclusions:</b> <i>"Regionalization of complex surgical procedures was encouraged by the provincial cancer agency and promoted through continuing education of practicing surgeons using formal presentations and informal mechanism including Communities of Practice. These initiatives were associated with a reduction in the total number of hospitals doing pancreatic surgery, a shift in cases from low to higher volume hospitals, and a decrease in both overall provincial mortality rates and mortality within each of the volume categories. It is our belief that the change in outcomes was the result of all of these initiatives together rather than any of them independently, and this coordinated systematic provincial quality improvement strategy is currently being applied in other disease states."</i></p>
Riall (2007)	<p><b>Pancreas resection in Texas:</b></p> <ul style="list-style-type: none"> <li>Texas inpatient discharges for 1999-2004;</li> <li>Indications: periampullary adenocarcinoma, pancreatic, other benign and malignant conditions;</li> <li>Excluded patients: out of state or country address, &lt; 18 years;</li> <li>Distance from home to hospital of surgery and distance to nearest HVH calculated from zip codes;</li> </ul>	<p><b>3,180 procedures during study period:</b></p> <ul style="list-style-type: none"> <li>1,254 (87.8%) at teaching hospitals;</li> <li>Unadjusted in-hospital mortality: HVH, 3.0%; LVH, 7.4%;</li> <li>Resections at HVHs: 1999, 63.3%; 2004, 64.3%; <math>P = 0.0004</math>;</li> <li>Multivariate analysis for independent predictors of treatment at HVHs: age &gt; 75 (OR, 0.51); female (OR, 0.86); Hispanic (OR, 0.58); emergent surgery (OR, 0.39); peri-ampullary lesion (OR, 0.68); living &gt; 75 miles from HVH (OR, = 0.93 for each 10 mile increase in distance; <math>P &lt; 0.04</math> for all ORs;</li> </ul>

Reference	Objectives/other details	Results/Comments
	<ul style="list-style-type: none"> <li>Hospitals classified by Leapfrog Standards: HVH<math>\geq</math>1 procedures/year Vs &lt; 10.</li> </ul>	<ul style="list-style-type: none"> <li>Odds of treatment at HVH increased 6% per year;</li> </ul> <p><b>Conclusions:</b> <i>"Whereas regionalization of pancreatic resection in the state of Texas has improved slightly over time, 37% of patients continue to undergo resection at low-volume centers, with more than 25% occurring at centers doing less than five per year. There are obvious demographic disparities in the regionalization of care, but additional barriers need to be identified."</i></p>
Barrett (2005)	<p><b>Newfoundland and Labrador provinces, Canada:</b></p> <ul style="list-style-type: none"> <li>Hospital discharge and day surgical data for 1995-2001,</li> <li>Acute care services were regionalized in 1995, with hospital closure and relocation; resulting in most tertiary care and greatest concentration of hospitals in St. John's area.</li> </ul>	<p><b>Changes during and after regionalization:</b></p> <ul style="list-style-type: none"> <li>Admissions declined by 14% in St. John's Vs 17% elsewhere;</li> <li>Inpatient days fell by 9% in St. John's Vs 12% elsewhere;</li> <li>Average LOS and resource intensity weight changed little, apart from final year, with largest change in St. John's: standardized hospital admission rates declined by 10% and inpatient days by 5.6%;</li> <li>No change over time in use of day surgery.</li> </ul> <p><b>Conclusions:</b> <i>The degree to which acute care restructuring or financial pressures and constraints imposed at the provincial level contribute to observed utilization rates is unclear. Aggregation of hospitals in the St. John's region may have contributed to more efficient use of acute care beds. Restructuring as carried out did not integrate health sectors, and problems in acute care/continuing care boundary were not resolved in St. John's, where access to continuing care remained difficult."</i></p>
Long (2003)	<p><b>Craniotomy for tumors in regional academic referral centers:</b></p> <ul style="list-style-type: none"> <li>Maryland state database;</li> <li>Adult patients, 1990-1996;</li> <li>33 non-federal acute care hospitals: two volume categories;</li> <li>Adjustments for patient demographics and comorbid conditions</li> </ul>	<p><b>4723 procedures during study period:</b></p> <ul style="list-style-type: none"> <li>Mortality: LVH, 4.9%; HVH, 2.3%; adjusted RR, 1.4(P&lt;0.05);</li> <li>LOS: LVH, 8.8 days; HVH, 6.8 (P&lt;0.001);</li> <li>Adjusted mean total charges: HVH, \$15,867; LVH, \$14,45 (P&lt;0.001).</li> <li>If all patients had been treated at HVHs, 48.6% fewer patients would have died, at an additional cost of \$76,395 per patient saved.</li> </ul> <p><b>Conclusions:</b> <i>"High-volume regional medical centers are capable of providing services with improved mortality rates, although with adjusted costs slightly higher than those at low-volume hospitals."</i></p>

**Table 3: What do we know about the underlying causes of the volume/experience effect?**

- other associations for improved outcomes
- Statistical/analysis issue

Reference	Study purpose/design	Results/comments
Egorova (2008)	See Table 1; section a	
Gooden (2008)	<b>Effect of provider volume on racial outcome differences after radical prostatectomy:</b> <ul style="list-style-type: none"> <li>• Medicare database, surgery for prostate cancer within 6 months of diagnosis, 1993-1999;</li> <li>• Regression: volume tertiles, recurrence or death, race, grade, comorbidity index.</li> </ul>	<b>963 black patients; 7387 white:</b> <ul style="list-style-type: none"> <li>• Recurrence-free survival improved with hospital and surgeon volume;</li> <li>• Blacks more likely to experience recurrence; HR, 1.34; (CI, 1.20-1.50);</li> <li>• Stratification by hospital volume: differences persisted within medium and high volume hospitals with adjustment; HRs, 1.30 (CI, 1.04-1.61); and 1.36 (CI, 1.07-1.73) respectively;</li> <li>• Racial difference persisted for medium and high volume surgeons: HRs, 1.43(1.10-1.85); and 1.57 (1.14-2.16) respectively;</li> </ul> <p><b>Conclusions:</b> <i>“High hospital and physician volumes were not associated with reduced racial differences in recurrence-free survival after prostate cancer surgery, contrary to expectation. This study suggests that social and behavioral characteristics, and some aspects of access, may play a larger role than organizational or systemic characteristics with regard to recurrence-free survival for this population.”</i></p>
Gutierrez (2008)	<b>To compare treatment patterns and long-term outcomes between teaching hospitals and community hospitals treating patients with infiltrating ductal carcinoma:</b> <ul style="list-style-type: none"> <li>• Florida cancer registry, 1994-2000;</li> <li>• Cross-sectional: outcomes and practice patterns at teaching hospitals Vs community hospitals of different volumes;</li> <li>• Frequencies and multivariate analyses.</li> </ul>	<b>24,834 operative cases</b> (2,816 in teaching hospitals, 22,018 community): <ul style="list-style-type: none"> <li>• 41.3% high grade tumors; 6.1% &gt; 5 cm at diagnosis; 31.0% regionally advanced; 2.6% distant metastases;</li> <li>• Patients at teaching hospitals were younger (59 Vs 67, P&lt;0.001); and higher proportion non-white (13.2% Vs. 7.4%, P&lt;0.001);</li> <li>• Patients at teaching hospitals more likely to have high grade tumors (47.% Vs. 40.5%, P&lt;0.001), large tumors (10.1% Vs. 5.6%, P&lt;0.001), and regionally advanced or metastatic disease (36.2% Vs 30.4%, P&lt;0.001);</li> <li>• No differences in number of lymph nodes examined or number of positive nodes;</li> <li>• Payers: larger percentages of uninsured and Medicaid patients at teaching hospitals (7.7% and 4.8% Vs 2.3% and 1.7%, P&lt;0.001);</li> <li>• Teaching hospitals treated 11.3% of patients and larger proportion of stage III/IV disease: 39.8% Vs 33.0% in non-teaching;</li> </ul> <p><b>Differences in surgical and adjuvant treatment:</b></p> <ul style="list-style-type: none"> <li>• Greater percentage of breast conserving procedures in teaching hospitals(41.5% Vs 38.9%, P = 0.008);</li> <li>• Sentinel node biopsies equivalent in both types of hospital;</li> <li>• Radiation more frequent in teaching hospitals (31.9% Vs 26.5%, P&lt;0.001);</li> </ul>

Reference	Study purpose/design	Results/comments
		<ul style="list-style-type: none"> <li>chemotherapy more frequent (44.4% Vs.22.9%<math>P&lt;0.001</math>);</li> <li>Hormone therapy more frequent (30.1% Vs 18.3%, <math>P&lt;0.001</math>);</li> <li>No difference in time from diagnosis to surgery or treatment;</li> </ul> <p><b>Outcomes:</b></p> <ul style="list-style-type: none"> <li>5- and 10-year survival rates significantly higher in teaching hospitals than in high- or low-volume community hospitals (84% and 72% Vs 81% and 69% or 77% and 63% respectively; <math>P&lt;0.001</math>);</li> <li>Patients with metastatic disease did better at teaching than at either volume community hospital (47% at 5 yrs and 40% at 10 yrs Vs 25% and 15% respectively; <math>P&lt;0.001</math>);</li> <li>Patients with high grade tumors and/or large tumors did better at teaching hospitals.</li> </ul> <p><b>Conclusions:</b> <i>"Patients with IDC treated at teaching hospitals have significantly better survival than those treated at high-volume centers or community hospitals, particularly in the setting of advanced disease. Poorer long-term outcomes for IDC at community hospitals seem to be, at least in part, because of decreased use of proven life-extending adjuvant therapies. These results should encourage community hospitals to institute changes in treatment approaches to invasive breast cancer to optimize patient outcomes."</i></p>
Kim (2008)	<p><b>Does volume-outcome relationship for CABG differ by race?</b></p> <ul style="list-style-type: none"> <li>93 UHC hospitals, 2002-2005;</li> <li>Logistic regression across 4 Volume categories: &lt; 100/yr; 100-299/yr; 300-499/yr; &gt; 500/yr;</li> <li>Analyses controlled for patient risk, geographic region; proportion of African Americans treated;</li> </ul>	<p><b>71,949 CABG procedures:</b></p> <ul style="list-style-type: none"> <li>In hospital mortality: whites, 2.0%; black, 2.8%;</li> <li>Benefit for higher volume substantial for blacks, modest for whites: race-by-volume interaction <math>P = 0.033</math>;</li> <li>ORs for mortality among blacks by volume categories: low Vs very low, 0.46; medium Vs very low, 0.37; high Vs very low, 0.47; among whites, 0.85; 0.77; 0.75 respectively;</li> <li>Racial disparities in mortality mostly in low volume hospitals;</li> <li>Differential volume effect apparently driven mostly by regional patterns and more pronounced in South and Midwest region by volume interaction, <math>P = 0.033</math>).</li> </ul> <p><b>Conclusions:</b> <i>"Blacks have greater reduction in mortality than whites by undergoing CABG at higher-volume hospitals, regardless of operative risk. Because of limited generalizability, these findings should be confirmed using more representative databases."</i></p>
Nazarian (2008)	Table 1	
Vernooij (2008)	<p><b>hospital type and survival of ovarian cancer patients:</b></p> <ul style="list-style-type: none"> <li>Netherlands Cancer Registry linked to death records, 1996-2003;</li> <li>Controls: same-age women from population</li> </ul>	<p><b>8,621 women with epithelial ovarian cancer:</b> 40% treated in general hospitals, 41% semi-specialized, 38.0% in specialized;</p> <ul style="list-style-type: none"> <li>5-year overall survival by hospital type; general, 38.0% (CI, 36.0-39.9); semi-specialized, 39.4% (CI, 37.5-41.4); specialized, 40.3% (CI, 37.4-43.1);</li> <li>Age and cancer stage associated with relation between hospital type and survival, but not</li> </ul>

Reference	Study purpose/design	Results/comments
	<ul style="list-style-type: none"> <li>Hospital type: general, semi-specialized, specialized;</li> <li></li> </ul>	<p>histologic tumor type, grade, year of diagnosis or socioeconomic status;</p> <ul style="list-style-type: none"> <li>Patients with early-stage disease: treatment in semi-specialized and specialized hospitals associated with lower risk of cancer-specific mortality than in general hospitals;</li> <li>Early stage patients 50-75 yrs: cancer-specific mortality 30% lower for semi-specialized hospitals, 40% lower for specialized;</li> <li>Advanced ovarian cancer: hospital type not associated with survival.</li> </ul> <p><b>Conclusions:</b> <i>Hospital type was statistically significantly associated with survival among Dutch ovarian cancer patients with early-stage ovarian cancer. Patients who were treated in specialized and semi-specialized hospitals survived longer than patients treated in general hospitals."</i></p>
Yermilov (2008)	See Table 2	
Glance (2007)	See Table 2	
McPhee (2007)	See Table 2	
Gutierrez (2007b)	<p><b>Surgery for rectal cancer at teaching Vs community hospitals:</b></p> <ul style="list-style-type: none"> <li>Florida cancer registry, 1994-2000;</li> <li>Adjusted for: patient demographics, stage and grade of disease,;</li> <li>Hospital teaching status according to AAMC</li> </ul>	<p><b>5,925 surgical cases during study period:</b></p> <ul style="list-style-type: none"> <li>8 teaching hospitals treated 12.5% of patients; 288 community hospitals treated 87.5%;</li> <li>Median patient age 69; 92.7% white; regionally advance disease in 53.6%; distant metastases in 9.6%;</li> <li>Median FU, 68 months for entire cohort; 93 months for survivors only;</li> <li>5- and 10-year survival: 64.8% and 53.9% at teaching hospitals; 59.1% and 50.5% at community hospitals (P = 0.002);</li> <li>Highest stage tumors: m30.5% at 5 years, 26.6% at 10 yrs in teaching hospitals; 19.6 % and 17.4% in community hospitals (P = 0.009);</li> <li>Multimodality therapy and low anterior resection more frequent at teaching hospitals;</li> <li>Multivariate analyses: significantly better survival at teaching hospitals (HR, 0.834; P = 0.005).</li> </ul> <p><b>Conclusions:</b> <i>"Rectal cancer patients treated at teaching hospitals have significantly better survival than those treated at community-based hospitals. Patients with high-grade tumors or advanced disease should be provided the opportunity to be treated at a teaching hospital."</i></p>
Vernooij (2007)	See Table 1	
Long (2006)		
Welke (2006)		
Alter (2005)		
Urbach (2005)	See Table 1, Section A	
Birkmeyer (2005)	<p>Cross-sectional analysis:</p> <ul style="list-style-type: none"> <li>National Medicare database, 1994-99;</li> <li>Mortality and 5-yr survival for resections of cancers:</li> </ul>	<p><b>63,860 elderly patients underwent the procedures:</b></p> <ul style="list-style-type: none"> <li>NCI cancer centers had lower adjusted surgical mortality than controls for 4/6 procedures: colectomy (5.4% Vs 6.7%; P = 0.0260); pulmonary resection (6.3% Vs. 7.9%; P = 0.010);</li> </ul>



Reference	Study purpose/design	Results/comments
	lung, esophageal, gastric, bladder, or colon; <ul style="list-style-type: none"> <li>51 NCI cancer centers and 51 control hospitals with highest volumes for those procedures;</li> <li>Outcomes adjusted for patient characteristics and residual differences in volume</li> </ul>	gastrectomy (8.0% Vs. 12.2% ; P = 0.001); and esophagectomy (7.9% Vs 10.9%; P = 0.027); <ul style="list-style-type: none"> <li>NS trends toward lower adjusted mortality at NCI centers for cystectomy and pancreatic resection;</li> <li>Among patients surviving surgery, there were no important differences in subsequent 5-year survival for any of the procedures.</li> </ul> <p><b>Conclusions:</b> <i>"For many cancer procedures, patients undergoing surgery at NCI-designated cancer centers had lower surgical mortality rates than those treated at comparably high-volume hospitals, but similar long-term survival rates."</i></p>
Zacharias (2005)	<b>Outcomes after CABG: multivariate risk-Vs propensity-adjusted outcomes:</b> <ul style="list-style-type: none"> <li>5 surgeon team (Toledo, Ohio), 2001-2003;</li> <li>Excluded patients: concomitant valve other cardiac, or carotid surgery;</li> <li>Two hospitals: LVH (160/yr); HVH (487/yr): compared with STS outcomes</li> </ul>	<b>3,115 open heart procedures during study period; 2269 isolated CABG:</b> <ul style="list-style-type: none"> <li>Mean surgeon volume: 178 open heart procedures (range 161-285);</li> <li>Isolated CABG: HVH, 1410; LVH, 504;</li> <li>Multiple demographic and risk differences between hospitals: unadjusted mortality: LVH, 2.38%; HVH, 2.98%; P = 0.59; similar to each other and to STS results for same period;</li> <li>Hospital volume did not predict operative mortality: OR, 0.82; P = 0.602;</li> <li>Unadjusted 3-yr survival significantly worse at HVH: RR, 1.59; CI, 1.06-2.39; P = 0.026);</li> <li>Procedure volume not independently associated with worse midterm outcome after covariate adjustment (RR, 1.28; CI, 0.84-1.96; P = 0.247) or propensity score (RR, 1.11; CI, 0.72-1.71; P = 0.648);</li> </ul> <p><b>Conclusions:</b> <i>"Hospital and surgeon volume effects are interdependent, and therefore hospital coronary artery bypass grafting volume per se is not a reliable marker of quality. Instead, outcome quality markers should rely on thorough risk-adjustment based on detailed clinical data, possibly including annual and cumulative surgeon volume."</i></p>
Dimick (2004c)	Are procedures for which mortality has been advocated as a quality indicator by AHRQ (CABG, AAA repair, pancreatic resection, esophageal resection, pediatric heart surgery, craniotomy, hip replacement) performed frequently enough to identify hospitals with increased rates? NIS for 2000: <ul style="list-style-type: none"> <li>All discharges from nationally representative (for region, number of beds, teaching status, urban Vs rural, ownership) sample of 994 hospitals;</li> <li>US national weighted average mortality rates and hospital caseloads for seven operations with assumption of constant caseloads over time;</li> <li>Sample size calculation for each procedure to</li> </ul>	<b>National average mortality rates:</b> <ul style="list-style-type: none"> <li>From 0.3% (hip replacement) to 10.7% (craniotomy);</li> <li>Minimum caseloads to detect doubling of mortality rate: craniotomy, 64 cases; esophageal resection, 77; pancreatic resection, 86; pediatric heart surgery, 138; AAA repair, 195; CABG, 219; hip, 2668;</li> <li>For only one procedure did majority of hospitals exceed the minimum caseload: 90% of hospitals performing CABG met minimum; craniotomy, 33%; pediatric heart, 25%; AAA repair, 8%; pancreas, 2%; esophagus, 1%; hip &lt; 1%.</li> </ul> <p><b>Conclusions:</b> <i>"Except for CABG surgery, the operations for which surgical mortality has been advocated as a quality indicator are not performed frequently enough to judge hospital quality."</i></p>

Reference	Study purpose/design	Results/comments
	<p>determine minimum caseload necessary to reliably detect increased mortality;</p> <ul style="list-style-type: none"> <li>Benchmark was national average mortality (death during index hospitalization) for each procedure;</li> </ul>	
Epstein (2004)	See Table 1, section a.	
Elixhauser (2003)	<p><b>Volume, mortality, and associated, hospital and staffing characteristics:</b></p> <ul style="list-style-type: none"> <li>10 complex procedures (AAA repair, CEA, lower extremity arterial bypass, CABG, coronary angioplasty, heart transplantation, pediatric heart surgery, esophageal cancer surgery, cerebral aneurysm surgery);</li> <li>NIS for 2000;</li> <li>Hospital weights</li> <li>Volume thresholds based on Dudley (2000).</li> </ul>	<p><b>994 NIS hospitals with 7,450,992 discharges in 2000:</b></p> <ul style="list-style-type: none"> <li>For 7/10 procedures, &gt; 75% of hospitals were low-volume;</li> <li>Most procedures are done in high volume hospitals, but most hospitals perform then at low-volume levels because of wide differences in number of procedures performed by high-Vs low-volume hospitals</li> <li>Only for heart transplant and lower extremity arterial bypass: at least half of hospitals reached high-volume threshold.</li> <li>For most procedures, low volume hospitals treat fewer than half of all patients receiving these procedures.</li> <li>Esophageal cancer, cerebral aneurysm, pancreatic cancer, and AAA repair: most patients had procedures at low volume hospitals.</li> <li>Across all ten procedures: 27% at low-volume hospitals.</li> <li>Unadjusted mortality for half of all procedures was higher at low-volume hospitals (1.5 times high-volume mortality).</li> </ul> <p><b>Staffing intensity and expertise:</b></p> <ul style="list-style-type: none"> <li>4 procedures: low volume hospitals had lower numbers of residents and interns/bed; for 8 procedures, lower RN staffing rates;</li> <li>Low –volume hospitals: small, urban, non-teaching, rural for-profit, or located in South.</li> </ul> <p><b>Conclusions:</b> <i>“This study shows that low-volume hospitals often perform very small numbers of procedures, whereas many high-volume hospitals perform far more than the threshold number...This suggests that policy makers and others interested in an incremental approach to volume-based (or concerned that methodological problems create uncertainty about how to handle hospitals near the threshold levels) might be able to identify some very low-volume hospitals as a starting point for changing referral patterns. One caveat of this study lies in the precise thresholds for these procedures based upon the results of a single literature review that surveyed numerous studies and determined the threshold based on the highest-quality studies. Future analyses and policies based on the volume-outcome literature should explore alternative thresholds to assess whether different thresholds would result in much different definitions of high- and low-volume hospitals.”</i></p>

Reference	Study purpose/design	Results/comments
Katz (2003)	See Table 1; section a	
Pangeas (2003)	<p>Reanalysis of data from 3 previously published volume-outcome studies: data from SEER on procedures 1992-1996:</p> <ul style="list-style-type: none"> <li>• 24,166 colectomies by 2682 surgeons;</li> <li>• 10,737 prostatectomies by 999 surgeons;</li> <li>• 2,603 rectal resections by 1141 surgeons;</li> <li>• Volume-outcome trends analyzed by conventional logistic regression and two methods for analysis of clustered data: random effects and GEE;</li> <li>• graphical representations of clustering (the tendency of patients of one provider to have similar outcomes).</li> <li>• Outcomes: 2 year mortality or procedure-specific complications</li> </ul>	<p><b>Substantial clustering of morbidity outcomes was apparent:</b></p> <ul style="list-style-type: none"> <li>• Two methods for analysis of clustering produced different results in some analyses;</li> <li>• Colon cancer: correction for clustering widened CI for volume effects</li> <li>• Prostate cancer: effects of clustering pronounced for prostatectomy but volume-outcome trends remained significant after correction for clustering.</li> <li>• Rectal cancer: significance of volume was eliminated by correction for clustering.</li> </ul> <p><b>Conclusions:</b> <i>"The presence if clustering represents variations in outcomes among providers with similar volumes. Thus, in volume-outcome studies, the degree of clustering of outcomes should be characterized because it may provide insight into variations in quality of care."</i></p> <p><b>Implications:</b> <i>"Planners considering regionalizing surgery should remember that volume-outcome studies that have not accounted for clustering exaggerate differences in outcomes by provider."</i></p>
Khuri (1998)	National VA Surgical Quality improvement Program	<p>417,944 procedures during FY97:</p> <ul style="list-style-type: none"> <li>• 11 VAMCs were low outliers for risk-adjusted O/E mortality;</li> <li>• 13 were high outliers;</li> <li>• Identification of high or low outliers by unadjusted mortality rates would have ascribed outlier status incorrectly to 25 of 39 hospitals (64% error rate);</li> <li>• Since 1994, the 30-day morbidity and mortality rates for major surgery have fallen by 9% and 30%, respectively.</li> </ul> <p><b>Conclusions:</b> <i>"Reliable, valid information on patient pre-surgical risk factors, process of care during surgery, and 30-day mortality is available for all major surgical procedures in the 123 VAMCs performing surgery in the VHA. With this information, the VHA has established the first prospective outcome-based program for comparative assessment and enhancement of the quality of surgical care among multiple institutions for several surgical subspecialties. Key features to the success of the NSQIP are the support of surgeons who practice in the VHA, consistent clinical definitions and data collected by dedicated nurses, a uniform nationwide electronics system, and the support of VHA administration and managerial staff."</i></p>

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## TECHNOLOGY ASSESSMENT PROGRAM

### Mission Statement

To enhance the health of veterans and the nation by providing and fostering technology assessment for evidence-based health care

### Values

***Integrity and pride*** in the work that we do

***Quality*** products that are clinically valid and methodologically transparent

***Objectivity*** in evaluating and presenting research evidence

***Commitment*** to continuous quality improvement and to the guiding principles of evidence based practices

***Flexibility*** in responding to changes in VA and the larger healthcare environment

***Innovation*** in designing products and their dissemination to best meet VA's needs

***Accessibility*** of products and services